PREPARE THE MATERIALS

MATERIALS PROVIDED:

- A Swab
- A Test Tube with Buffer
- A Test Tube with Solution
- 1x Mask
- 1x Test Card
- 5x Swabs
- 5x Test Tubes
- 1x Timer

DO NOT open the test contents until ready for use. Once opened, the test device should be used immediately.

PERFORM THE TEST

1. Remove the Test Card from its foil pouch.
2. Place the swab into the extraction solution making sure the swab head is completely immersed.
3. Squeeze the swab solution by rotating the swab vigorously against the inside walls of the nostril, making at least 5 circles.
4. Place the swab into the extraction solution making sure the swab head is completely immersed.

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

5. Add 5 drops of the extraction solution to the sample well on the test card, and place the card vertically over the sample well. If any other line is visible in the results window, the test is invalid. DO NOT read the result before 15 minutes.

NOTE: Failure to rotate the tube may lead to false negative results.

6. Hold the dropper VERTICALLY over the sample well on the test card, squeeze out exactly 5 drops of the solution.
7. Do NOT insert the swab any farther if you feel any resistance.

NOTE: The image displayed above is one example only; additional invalid outcomes are possible. To interpret the complete set of invalid results to go to co-infection with other viruses. The agent detected may also need to be considered null.

NOTE: Failure to rotate the sample well may lead to false negative results.

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

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

NOTE: Any pink or purple line on the correct.

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

NOTE: Failure to rotate the tube may lead to false negative results.

STOP: Did you swab BOTH nostrils?

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

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

NOTE: Failure to rotate 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.

NOTE: Failure to rotate the tube may lead to false negative results.

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

NOTE: Any pink or purple line on the correct.

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

NOTE: The virus from COVID-19, Flu A, and/or Flu B may be 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 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 individuals with a history of COVID-19 infection. If you tested negative, you should 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.

RESULT REPORTING

Report your test result(s) at yourcovidtest.org. This voluntary and anonymous surveillance program helps teams understand COVID-19 spread in your area, and across the country, and informs public health decisions.

After you test, please dispose of all test materials in household trash and wash hands.
The 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 viruses. This test is not intended to be used with SARS-CoV-2, influenza A, and influenza B viruses to detect other viruses or pathogens.

**INTENDED USE**

The COVID-19/Flu A&B Rapid Test is for use by 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 if they have symptoms of COVID-19 and initial negative results should be tested again after 48 hours. You may need to choose 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 you have a SARS-CoV-2 negative result, it is recommended to continue serial testing to determine infection status.

**WARNINGS, PRECAUTIONS AND 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 FDA authorized 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, for not other viruses or pathogens. The emergency use of this product is only authorized for the duration of the declaration that circumstances exist to justify the authorization of emergency use. The declaration, under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, as amended by the Pandemic and All-Hazards Preparedness Act, 368(b)(1)(E), unless the declaration is terminated or authorized is reversed.
- Serial testing should be performed in individuals with SARS-CoV-2 negative results at least twice over three days (three to four days between tests) to improve test sensitivity.
- You may need to purchase additional tests to perform this serial testing.
- Consistent with various recommendations for SARS-CoV-2, for multi-analyte tests, symptomatic individuals who test positive for influenza A or B, are asymptomatic and are isolated, should be tested again in 48 hours to evaluate for co-infection.
- For an anterior nasal swab sample can be self-collected by an individual aged 14 years or older. Children aged 2 to 13 years should be tested by a trained healthcare provider. 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 any of the test kit components or packaging damaged.
- For more information on FDA please visit: https://www.fda.gov/COVID19

**STORAGE AND STABILITY**

Store the test between 34°F to 79°F (1°C to 26°C) in a place out of direct sunlight. Reagents and devices must be used at room temperature (68°F/20°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 23, 2020 to January 24, 2021. The clinical performance has not been established for all circumstances. It is anticipated to be lower in the variant prevalence in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variant circulating, including newly emerging strains of COVID-19 and influenza and their prevalence, which changes over time.

There is a higher chance of false negative results with antigen tests than with laboratory-based molecular tests due to the nature of the test. False negative results may occur if there is that there is a higher chance this test will give a false negative result for 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 A or B, for not other viruses or pathogens. False negative results may occur if there is a lower chance this test will give a false negative result when you have a COVID-19 and influenza test.

**WHAT IF I HAVE A COVID-19 NEGATIVE TEST RESULT?**

A: This test is read visually and has not been validated for use with those with impaired vision or color-impaired vision.

- The use of over-the-counter supplements and use of both as a topical application may impact the performance of the test. Instruct the patient to both may cause false negative results with this test.
- Based on sequence analysis, a potential for cross-reactivity between the SARS-CoV-2 test and H1N1v. After testing was completed, the test was conducted and therefore, cross-reactivity between SARS- CoV-2, H1N1v and other viruses is not expected with this test.
- This device is a qualitative test and does not provide information on the viral load present in the specimen. Increased test results may occur (a specimen is incorrectly collected or handled).

**FREQUENTLY ASKED QUESTIONS**

Q: **WHAT ARE THE KNOWN POTENTIAL RISKS AND BENEFITS?**

- Potential risks include:
  - False negative results could occur as you may not have COVID-19 even if you test negative. A negative test result does not rule out COVID-19 infection in the future. To reduce the risk of incorrect results, for more information on the risk of incorrect results, please apply to, please refer to the performance data in the Healthcare Provider Instructions for use (for US), available at https://www.cdc.gov/COVID19.

- Potential benefits include:
  - The results, along with other information, can help you and your healthcare provider make informed decisions about your care.
  - These devices are one-time use and may limit the spread of COVID-19 and flu to the family and the test kit that are used.

Q: **WHATS THE DIFFERENCE BETWEEN AN ANTIGEN AND MOLECULAR TEST?**

- There is a higher chance of false negative results with antigen tests than with laboratory-based molecular tests due to the nature of the test. False negative results may occur if there is a lower chance this test will give a false negative result when you have a COVID-19 and influenza test.

Q: **WHAT IF I HAVE A COVID-19 POSITIVE TEST RESULT?**

- For a positive result means that you have confirmed COVID-19 because proteins from the virus that causes COVID-19 are detected in your sample. However, if you have symptoms of COVID-19, and your first test result is negative, you should test again in 48 hours since antigen tests are not as sensitive as molecular tests. You do not have symptoms and received a negative result.

Q: **WHAT IF I HAVE A COVID-19 NEGATIVE TEST RESULT?**

- For a positive result means that you have confirmed COVID-19 because proteins from the virus that causes COVID-19 are detected in your sample. However, if you have symptoms of COVID-19, and your first test result is negative, you should test again in 48 hours.
iHealth COVID-19/Flu A&B Rapid Test

For use under Emergency Use Authorization (EUA) only.

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 use under Emergency Use Authorization (EUA) only.

Items necessary to use the test but not provided in the test kit: timer or clock.

Do not use if you have had symptoms longer than 4 days or no symptoms at all. 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 x COVID-19/Flu A&B Test Card; 1 x Tube; 1 x Swab

Manufactured for iHealth Labs, Inc. Made in China

880 W Maude Ave, Sunnyvale, CA 94085 USA 1-855-816-7705 www.ihealthlabs.com

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.

Model: ICF-3000
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 pathogens 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.

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
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.

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.

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.

Items necessary to use the test but not provided in the test kit: timer or clock.

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 x COVID-19/Flu A&B Test Card
- 3 x Tube
- 3 x Swab

Manufactured for iHealth Labs, Inc.

For more information, please visit www.ihealthlabs.com
iHealth COVID-19/Flu A&B Rapid Test

Rapid Self-Test
Results In 15 Mins

Components
COVID-19/Flu A&B Test Card
Tube
Swab

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.

Contents
4 x COVID-19/Flu A&B Test Card; 4 x Tube; 4 x Swab
Manufactured by iHealth Labs, Inc.
1-855-816-7705 www.ihealthlabs.com
880 W Maude Ave, Sunnyvale, CA 94085 USA
Made in China

UDI
UPC

Model: ICF-3000
COVID-19/Flu A&B Rapid Test

Components

- COVID-19/Flu A&B Test Card
- Tube
- Swab

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 less than 12 years of age.

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

- 5 x COVID-19/Flu A&B Test Card
- 5 x Tube
- 5 x Swab

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

Model: ICF-3000
• 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.

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

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

UDI
Made in China
1-855-816-7705 www.ihealthlabs.com

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.

Components

- COVID-19/Flu A&B Test Card Tube
- Swab

For use under Emergency Use Authorization (EUA) only.

- Use the iHealth COVID-19/Flu A&B Rapid Test for non-patient home use with self-collected anterior nares nasal swab specimen from individuals aged 14 years or older, or with adult-affected anterior nasal specimens from individuals 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 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.

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

If you receive a negative test result, additional testing may be needed. 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 had symptoms longer than 4 days or no symptoms at all.

For more information about current expiration dates for at-home OTC COVID-19/influenza diagnostic tests, please visit: http://www.fda.gov/medical-devices/over-the-counter-otc-covid-19-influenza-diagnostic-tests
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. § 360bb-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.

Items necessary to use the test but not provided in the test kit: timer or clock.

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

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

Model: ICF-3000

iHealth Manufacturing Inc.
15715 Arrow Hwy, Irwindale, CA 91706
iHealth COVID-19/Flu A&B Rapid Test

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.

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.

Contents
2 x COVID-19/Flu A&B Test Card; 2 x Tube; 2 x Swab

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

UDI

Model: KT-3000
iHealth Manufacturing Inc.
19715 Arrow Hwy, Irwindale, CA 91706

UPC
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 ten (10) 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.

Items necessary to use the test but not provided in the test kit: timer or clock.

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

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

UDI
Model: ICF-3000
manufactured by
iHealth Manufacturing Inc.
15715 Arrow Hwy, Irwindale, CA 91706
Components

COVID-19/Flu A&B Test Card
Tube
Swab

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 aged 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 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.
Components

- COVID-19/Flu A&B Test Card
- Tube
- Swab

Instructions

1. Remove the foil pouch and insert the tube into one of the foiled tubes. Place the foiled tube in the pouch and remove the test card from the pouch.
2. Place the test card in the pouch and expel any air from the cartridge.
3. Add 4 drops (2 mL) of the extraction solution to the tube.
4. Insert the tube into the test card and hold it upright for 1 minute. Then remove the tube from the test card and discard it in the provided waste bag.
5. After 15 minutes, compare the result to the control line on the test card. Positive results can be confirmed with two lines (control and test line) visible. If only one line (control) appears, the result is negative.

Important Notes

- The test is intended 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 test is not intended for use by patients with risk factors for severe disease from respiratory pathogens.
- Determining a negative result requires multiple tests. You may need to purchase additional tests to perform serial testing.
- 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 x COVID-19/Flu A&B Test Card; 5 x Tube; 5 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
Components

- COVID-19/Flu A&B Test Card
- Tube
- Swab

iHealth COVID-19/Flu A&B Rapid Test

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.
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.

Components

- COVID-19/Flu A&B Test Card Tube
- Swab

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Contents

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

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Model: ICF-3000

UPC