PERFORMING THE TEST

1. Remove the swab from the pouch.
   Note: Be careful not to touch the swab tip (soft end) with hand.

2. Insert the entire soft end of the swab into the nostril no more than 3/4 of an inch (1.5 cm). Firmly and slowly rotate the swab 5 times, brushing against the inside walls of the nostril to ensure both mucus and cells are collected.
   • Do not push the swab further if you meet resistance.
   • For young children do not insert more than 1/2 inch.

3. Insert the swab into the tube until it touches the bottom.
   Rotate the swab at least 10 times while pressing the swab head against the bottom and side of the tube.

4. Remove the swab while squeezing the sides of the tube.
   Attach the dropper tip firmly onto the tube.

5. Slowly squeeze the tube and dispense 3 drops of solution into the sample well.
   Note: Invalid results can occur if less than 3 drops are added to the Sample Well.

6. Wait 10 minutes. Read the result after 10 minutes but before 30 minutes.
   Note: False results can occur if the test is read before 10 minutes or after 30 minutes.

INTERPRETING RESULTS

If the control line (C) is visible, but no other lines appear the test is negative.
To increase the chance that the negative result for COVID-19 is accurate, you should test again in 48 hours.
If you still have COVID-19, Flu B, Flu A, or symptoms, you should seek follow-up care with your healthcare provider.

POSITIVE RESULTS

If the control line (C) is visible and one or more lines appear for any of the viruses, the test is positive for that or those viruses.

NOTE: It is possible to have more than one positive test line, which could indicate a co-infection with influenza A, B, and/or SARS-CoV-2. If more than one positive test line is observed, repeat with a new sample and new test kit. If you continue to have a “dual positive” result, you should contact your healthcare provider to be tested with a molecular assay to confirm your results.

UNDERSTANDING YOUR RESULTS

INVALID RESULTS: The test could not tell whether or not 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 it is certain 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.

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.
**INTENDED USE**

The CorDx Tyfast Flu A/B & COVID-19 At Home Multiplex Rapid Test is a lateral flow immunoassay intended for the qualitative detection of SARS-CoV-2, influenza A, and influenza B protein antigens. This test is authorized for non-prescription home use with self-collected anterior 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 five (5) days of symptom onset when tested at least twice over three days at 48-hour intervals. Clinical signs and symptoms of respiratory viral infection due to SARS-CoV-2 and influenza can be similar. Results are for the identification and differentiation of SARS-CoV-2, influenza A, and influenza B virus protein antigens, but do not rule out viral coinfections. The test does not rule out bacterial infection or coinfection with other viruses. The agent detected may not be the definitive cause of disease. Individuals who test positive with the CorDx Tyfast Flu A/B & COVID-19 At Home Multiplex 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 patient management decisions, including infection control decisions such as isolating from others and wearing masks. Negative results should be considered in the context of other clinical information, and the presence of clinical signs and symptoms consistent with SARS-CoV-2, influenza A, and influenza B infection.

**WARNINGS, PRECAUTIONS AND SAFETY INFORMATION**

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

- **In the USA, this product has not been FDA cleared or approved, but has been authorized by FDA under an Emergency Use Authorization. This product has been authorized only for the detection of proteins from SARS-CoV-2, influenza A and influenza B, not for any other viruses or agents. This test is not approved by FDA only authorized for the duration of the declaration that contains the details 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-b(1)), unless the declaration is terminated or authorization is revoked sooner.**

- **Serial testing should be performed in symptomatic individuals with SARS-CoV-2 infection at least twice over three days (with 48 hours between tests). You may need to purchase additional tests to perform this serial (repeat) testing.**

- **Consistent with serial testing recommendations for SARS-CoV-2, for multi-analyte tests, symptomatic individuals who test negative for influenza A or B on the initial test but negative for SARS-CoV-2 should be tested again in 48 hours to evaluate for coinfection with SARS-CoV-2.**

- **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.**

- **Do not use the test kit after its expiration date.**

- **Do not touch swab tip when handling the swab. Exposing the test strip to hand sanitizer may cause false positive test results with this test.**

- **When collecting a sample, only use the swab provided in the test kit.**

- **Once opened, the test cassette should be used within 60 minutes. If the pouch is open for more than an hour, invalid test results may occur.**

- **Testing should be performed in an area with good lighting. Do not re-read test results before 10 minutes or after 30 minutes. Results read before 10 minutes or after 30 minutes may lead to a false positive, false negative, or invalid result.**

- **Faint lines may appear on the test strip prior to running the test when tests are stored opened at hot and humid conditions. Do not discard the test if a faint line appears on the test strip after the sample has been added to the test cassette and the test has been allowed to run for 10 minutes.**

- **Keep testing kits away from children and pets before and after use. Avoid contact with your skin, eyes, nose, or mouth. Do not ingest any kit components. The test cassette contains harmful chemicals (see table below). If the solution contacts your skin, eyes, nose, or mouth, flush with large amounts of water and consult instructions for use.**

**FREQUENTLY ASKED QUESTIONS**

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

A: Antigen tests are different kinds of tests for the COVID-19 and influenza virus. Molecular tests detect genetic material from the virus. Antigen tests, such as the CorDx Tyfast Flu A/B & COVID-19 At Home Multiplex Rapid Test, detect proteins from the virus that causes COVID-19 and influenza when taken multiple times across several days. Repeat testing improves test accuracy. This serial testing approach allows for the detection of more patients with a false negative result. For more information on the performance of the test and how the performance may apply to you, please refer to the performance data of the Healthcare Provider Instructions for Use (FU), available at CorDx.com.

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

A: A positive result means that it is very likely you have COVID-19 and influenza or that you have been infected with one of these viruses. If your COVID-19 or influenza 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 NEGATIVE TEST RESULT?**

A: A negative test result indicates that the viruses that cause COVID-19 and influenza were not detected in your sample. However, if you have symptoms of COVID-19 or influenza, and your first test is negative, you should test again in 48 hours after COVID-19 or influenza because proteins from the virus that causes COVID-19 or influenza may still be infected and you may still infect others. It is important that you follow your healthcare provider’s guidance to help you understand the next steps you should take.

**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 or if the test is invalid, a new test should be used to collect a new nasal specimen and you should test again. For more information on invalid results, visit your healthcare provider.

**Q: WHERE CAN I CHECK THE EXPIRATION DATE OF THE PRODUCT?**

A: You can find it on the side of the box. Please check the expiration date of the product before testing, and don’t use expired products for testing. For information about current expiration dates for at-home OTC COVID-19 diagnostic tests, visit http://www.fda.gov/covid-tests.

**INDEX OF SYMBOLS**

- **Do not re-use**
- **Keep dry**
- **Keep away from sunlight**
- **Store at 36–86°F/2–30°C**
- **Consult instructions for use**
- **Manufacturer**

**TECHNICAL SUPPORT**

For technical support, please email Support@CorDx.com or contact 858-999-1582.

**CorDx, Inc.**
**5155 Bluegrass Science Park Drive, Suite 100**
**San Diego, CA 92121**

**P202301 Rev 05.2 04/2024**
COMPONENTS

- Flu A/B & COVID-19
- At Home Multiplex Rapid Test
- Tyfast

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer or clock

For results interpretation, please refer to the instructions for use or visit CorDx.com

Tips

- For ages 2 years and older.
- Store sealed at 36-86°F/2-30°C.
- This test does NOT determine if you had COVID-19 in the past or if you have immunity.
- Persons with risk factors for severe disease from respiratory pathogens should consult and follow-up with a healthcare provider.
- For information about current expiration dates for at-home OTC COVID-19/influenza diagnostic tests, please visit: http://www.fda.gov/covid-tests

For in vitro diagnostic use
For Emergency Use Authorization (EUA) only
Do not use if you’ve had symptoms longer than 5 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.

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.

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.

Official label. For information on the complete EUA and labeling see: https://www.fda.gov/medical-devices/emergency-useauthorizations-euas/authorizations-sARS-CoV-2-tests
CorDx

Tyfast

Flu A/B & COVID-19
At Home Multiplex Rapid Test

COMPONENTS
2 Test cassettes
2 Swabs
2 Tubes with sample processing solution
1 Quick reference instructions

MATERIALS REQUIRED BUT NOT PROVIDED
Timer or clock

For results interpretation, please refer to the instructions for use or visit CorDx.com

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.

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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.

Pre-made hole for tube

CorDx

Tyfast

Flu A/B & COVID-19
At Home Multiplex Rapid Test

Press here to open

For Emergency Use Authorization (EUA) only
Do not use if you’ve had symptoms longer than 5 days or no symptoms at all

For ages 2 years and older.
Store sealed at 36-86°F/2-30°C.
This test does NOT determine if you had COVID-19 in the past or if you have immunity.

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

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

Flu A/B & COVID-19

At Home Multiplex Rapid Test

For diagnostic use
For Emergency Use Authorization (EUA) only

In vitro
Do not use if you've had symptoms longer than 5 days or no symptoms at all

For results interpretation, please refer to the instructions for use or visit CorDx.com

COMPONENTS
4 Test cassettes
4 Swabs
4 Tubes with sample processing solution
1 Quick reference instructions

MATERIALS REQUIRED BUT NOT PROVIDED
Timer or clock

CorDx, Inc.
9540 Waples St. #C
San Diego, CA 92121
Tel: +1-858-333-1122
Email: Info@CorDx.com
www.CorDx.com

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.

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

Box Label: 4 tests/box
File No.: Label-FluA/B&COVID-Box 4 V02

For ages 2 years and older.
Store sealed at 36-86°F/2-30°C.
This test does NOT determine if you had COVID-19 in the past or if you have immunity.
Persons with risk factors for severe disease from respiratory pathogens should consult and follow-up with a healthcare provider.

CorDx® is a trademark of CorDx, Inc.
COVID-19 is a respiratory disease caused by SARS-CoV-2, also known as 2019-nCoV.
Flu A/B & COVID-19 Multiplex Rapid Test

Fast Results

10 mins

CorDx

Components:
- 5 Test cassettes
- 5 Swabs
- 5 Tubes with sample processing solution
- 1 Quick reference instructions

Multi Target At Home

For diagnostic use
For Emergency Use Authorization (EUA) only

in vitro

Do not use if you've had symptoms longer than 5 days or no symptoms at all

5 Test cassettes
5 Swabs
5 Tubes with sample processing solution
1 Quick reference instructions

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.

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

For ages 2 years and older.
Store sealed at 36-86°F/2-30°C.
This test does NOT determine if you had COVID-19 in the past or if you have immunity.
Persons with risk factors for severe disease from respiratory pathogens should consult and follow-up with a healthcare provider.

MATERIALS REQUIRED BUT NOT PROVIDED
- Timer or clock
- Pre-made hole for tube

For in vitro diagnostic use
For Emergency Use Authorization (EUA) only
Do not use if you've had symptoms longer than 5 days or no symptoms at all

For results interpretation, please refer to the instructions for use or visit CorDx.com
Flu A/B & COVID-19 At Home Multiplex Rapid Test

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.

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

COMPONENTS

- 8 Test cassettes
- 8 Swabs
- 8 Tubes with sample processing solution
- 1 Quick reference instructions

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer or clock

For Emergency Use Authorization (EUA) only in vitro

For diagnostic use

Do not use if you’ve had symptoms longer than 5 days or no symptoms at all

For ages 2 years and older.

Store sealed at 36-86°F/2-30°C.

This test does NOT determine if you had COVID-19 in the past or if you have immunity.

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

This test was not cleared or approved by FDA under a premarket approval (PMA) submission. This product contains buffers and reagents formulated by Tyfast under a Deficiency Letter Authorization. Read and understand these instructions before use. Use only as directed. Results are specific only under the conditions specified in these instructions. If this product is used under other conditions, it may not provide correct results or safe performance.

Box Label: 8 tests/box File No.: Label-FluA/B&COVID-Box 8 V02

Website for patients: www.Cordx.com

For more information about current expiration dates for at-home OTC COVID-19/influenza diagnostic tests, please visit: http://www.fda.gov/covid-tests
Tyfast 10 Tests

Fast Results
10 mins

Flu A/B & COVID-19

10X 5X
Right nostril
Left nostril
3 Drops

Tips
For results interpretation, please refer to the instructions for use or visit CorDx.com

For information about current expiration dates for all home OTC COVID-19/Bacterial diagnostic tests, please visit: https://www.fda.gov/medical-devices

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

Informed consent must be obtained from the legal guardian of the participant who is less than the age of consent in accordance with all applicable Federal, state, and local laws.

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.

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.

Nasal Swab
Multi Target

For ages 2 years and older.

Store sealed at 36-86°F/2-30°C.

This test does NOT determine if you had COVID-19 in the past or if you have immunity.

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

For information about current expiration dates for all home OTC COVID-19/Bacterial diagnostic tests, please visit: https://www.fda.gov/medical-devices

Nasal Swab

At Home Multiplex Rapid Test

For Emergency Use Authorization (EUA) only

Nasal Swab

CorDx, Inc.
9540 Waples St. #C
San Diego, CA 92121
Tel: +1-858-333-1122
Email: Info@CorDx.com
www.CorDx.com

COMPONENTS

10 Test cassettes
10 Swabs
10 Tubes with sample processing solution
1 Quick reference instructions

MATERIALS REQUIRED BUT NOT PROVIDED

Timer or clock

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

Informed consent must be obtained from the legal guardian of the participant who is less than the age of consent in accordance with all applicable Federal, state, and local laws.

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.

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.

Nasal Swab

Multi Target

CorDx

Nasal Swab

For Emergency Use Authorization (EUA) only

Nasal Swab

For Emergency Use Authorization (EUA) only

Nasal Swab

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For Emergency Use Authorization (EUA) only

Nasal Swab

For Emergency Use Authorization (EUA) only

Nasal Swab
**Flu A/B & COVID-19**

**5X 5X Right nostril Left nostril 3 3 Drops**

**Tips**

For results interpretation, please refer to the instructions for use or visit CorDx.com

**10 min**

**Wait 10 mins**

**20 Tests**

**Fast Results**

**10 mins**

**Flu A/B & COVID-19 At Home Multiplex Rapid Test**

**Tyfast**

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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.

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 but a test based on nucleic acid.
Tyfast
25 Tests
3 in 1
Fast Results
10 mins
Flu A/B & COVID-19
Tyfast
5X
10X
Flu A/B & COVID-19
At Home Multiplex Rapid Test
Nasal Swab
Multi Target
For diagnostic use
For Emergency Use Authorization (EUA) only
in vitro
Do not use if you've had symptoms longer than 5 days or no symptoms at all

For ages 2 years and older.
Store sealed at 36-86°F/2-30°C.
This test does NOT determine if you had COVID-19 in the past or if you have immunity.
Persons with risk factors for severe disease from respiratory pathogens should consult and follow-up with a healthcare provider.
For information about current expiration dates for at-home OTC COVID-19/influenza diagnostic tests, please visit:
http://www.fda.gov/covid-tests

For results interpretation, please refer to the instructions for use or visit CorDx.com.

Tips
1. Squeeze the Nasal Swab firmly for 10 min.
2. Squeeze the Multi Target for 10 min.
3. Read the results at 10 min.

Components:
- 25 Test cassettes
- 25 Swabs
- 25 Tubes with sample processing solution
- 1 Quick reference instructions

MATERIALS REQUIRED BUT NOT PROVIDED
- Timer or clock
- Nasal Swab
- Multi Target

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.

Determining a negative result requires multiple tests. You may need to purchase additional tests or 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.