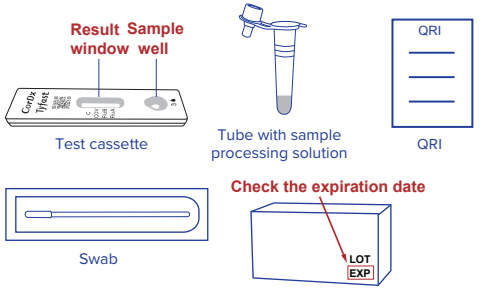
CorDx

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

KIT CONTENTS



MATERIALS REQUIRED BUT NOT PROVIDED:
Clock, timer or stopwatch.

TEST PROCEDURES

- Only the components provided in the test kit should be used.
- Transport media should not be used.
- It is recommended to use the test kit immediately after opening. The unsealed cassette is valid for 1 hour. Once the sample has been collected, it should be processed within 1 hour.

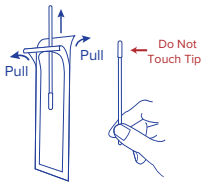
PREPARING FOR THE TEST

- Read all the instructions before you start the test.
- **Check the test's expiration date (EXP).**
  Do not use an expired test.
- Wash your hands with soap and water for 20 seconds and dry them thoroughly, or use hand sanitizer.

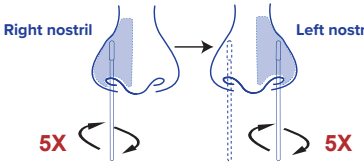
- Use a flat level surface (such as a table or countertop) for testing.
- Use a timer during the test.
- Make sure you have all the test components before you begin.
- Bring test kit to room temperature (59~86°F /15~30°C).
- Perform test at room temperature. Testing under conditions other than room temperature may lead to inaccurate results.

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.



Using the **same swab**, repeat this process for the other nostril to ensure an adequate sample is collected from both nostrils.

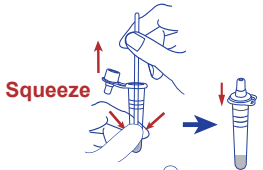
Did you swab BOTH nostrils?
Inaccurate test results may occur if the nasal sample is not properly collected.

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.

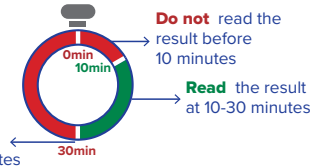
Attach the dropper tip firmly onto the tube.



5.
Slowly squeeze the tube and dispense 3 drops of solution into the sample well.

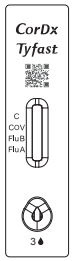
Note: Invalid results can occur if less than 3 drops are added to the Sample Well.

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

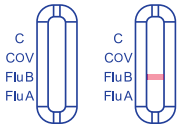


C = Control line
COV = COVID-19 line
Flu B = Influenza B line
Flu A = Influenza A line

Look for lines next to C, COV, Flu B, and Flu A.
FOR EASE OF USE, HOLD TEST CASSETTE NEXT TO THE IMAGES BELOW

INVALID RESULTS

If the control line (C) is not visible the test is **invalid**, even if any test line is visible. Re-test with a new swab and new test device.



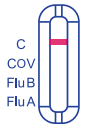
Note: The images displayed above are examples only; additional invalid outcomes are possible. For a complete set of invalid results, please visit *CorDx.com*

NEGATIVE 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.

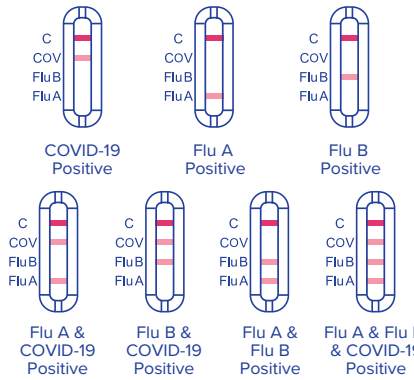
If you still have COVID-19, Flu B, Flu A, or symptoms, you should seek follow-up care with your healthcare provider.



POSITIVE RESULTS

If the control line (C) is visible and one or more lines appear(s) 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, retest 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.



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

POSITIVE RESULT: The COVID-19, Flu A and/or Flu B virus(es) were 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 can give you a positive result that is incorrect (a false positive).

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 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 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 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 identification and differentiation 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 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 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 CorDx Tyfast Flu A/B & COVID-19 At Home Multiplex 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.
- 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 symptomatic individuals with SARS-CoV-2 negative results 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 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 or open.
- 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.
- Exposure to hand sanitizer may cause false positive results with this test.
- When collecting a sample, only use the swab provided in the 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 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 read or interpret test results until after the sample has been added to the test cassette and the test has been allowed to run for 10 minutes.**
- **Keep testing kit and kit components 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 reagent solution contains harmful chemicals (see table below). If the solution contacts your skin, eyes, nose, or mouth, flush with large amounts of water. If irritation persists, seek medical advice: https://www.poisonhelp.org or 1-800-222-1222.**

Hazard Category (mixture)	GHS Hazard Statement for mixture	Labeling of Harm(s)	Hazardous Ingredients (%)	Recommended PPE Statement
3	Mild skin irritation	Cause mild skin irritation (H316)	• Triton X-100 / 0.5% • Proclin 300 / 0.05%	N/A

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

STORAGE AND STABILITY

Store the test kit between 36~86°F (2~30°C) in a place out of direct sunlight. Reagents and materials must be used at room temperature (59~86°F/15~30°C).

The unsealed cassette is valid for 1 hour. It is recommended to use the test kit immediately after opening.

The expiration date is labeled on the package.

LIMITATIONS

- The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between September 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 SARS-CoV-2 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 individual continues to have symptoms of COVID-19 or Influenza, and both the individual's first and second tests are negative, the individual may not have COVID-19 or Influenza infection, however additional follow-up may be needed.
- If the test is positive, then proteins from the viruses that causes COVID-19 or influenza infection have been found in the sample and the individual likely has a respiratory infection with COVID-19 or influenza.
- Incorrect test results may occur if a specimen is incorrectly collected or handled.
- Individuals who recently received nasally administered influenza A or influenza B vaccine may have false positive test results after vaccination.
- Based on sequence and epitope analyses, a potential for cross-reactivity between the SARS-CoV-2 test and HKU1 exist. Wet testing with HKU1 coronavirus was not conducted and therefore, cross-reactivity between SARS-CoV-2 and HKU1 coronavirus cannot be ruled out.
- False results due to cross-reactivity between Influenza B and SARS-CoV-2 can occur with this test at high viral loads/titers. If your test is positive for both SARS-CoV-2 and Influenza B, follow up testing with a molecular test (RT-PCR) should be performed by your healthcare provider to confirm results.
- This test is read visually and has not been validated for use by those with impaired vision or color-impaired vision.
- This test detects both viable (live) and nonviable SARS-CoV-2 and influenza. Test performance depends on the amount of virus (antigens) in the sample and may or may not correlate with viral culture results performed on the same sample.

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 sections WARNINGS, PRECAUTIONS AND SAFETY INFORMATION and INTERPRETING RESULTS 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 influenza 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 COVID-19 and influenza. 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. 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 and influenza than a molecular test would.

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 and influenza 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 *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 or influenza because proteins from the virus that causes 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 antigens from the virus 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 since antigen tests are not as sensitive as molecular tests. If you have a negative result, it does not rule out COVID-19 and influenza; 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: 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 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.

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

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.

INDEX OF SYMBOLS

	Do not re-use		Keep dry
REF	Catalogue number		Keep away from sunlight
	Store at 36~86°F/2~30°C		Consult instructions for use
	Manufacturer		Do not use if package is damaged and consult instructions for use

TECHNICAL SUPPORT

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

CorDx, Inc.
9540 Waples St. #C
San Diego, CA 92121

PI2023001 Rev.05.2 04/2024


CorDx
V02
CorDx
Tyfast
Flu A/B & COVID-19
1
Right nostril
Left nostril
5X
5X
2
10X
Squeeze
3
3 Drops
4
10
min
Wait 10 mins
5
C
COV
FluB
FluA
Tips
For results interpretation, please refer to the instructions for use or visit
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Pre-made hole for tube
CorDx
COMPONENTS
1 Test cassette
1 Swab
1 Tube with sample processing solution
1 Quick reference instructions
MATERIALS REQUIRED BUT NOT PROVIDED
Timer or clock
• 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
CorDx
Tyfast
Flu A/B & COVID-19
At Home Multiplex Rapid Test
Nasal Swab
Multi Target
Press here to open
3 in 1
Fast Results
10 mins
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
1 Test
CorDx, Inc.
9540 Waples St. #C
San Diego, CA 92121
Tel: +1-858-333-1122
Email: Info@CorDx.com
www.CorDx.com
CorDx
Tyfast
Flu A/B & COVID-19
At Home Multiplex Rapid Test


CorDx
V02
CorDx
Tyfast
Flu A/B & COVID-19
1
Right nostril
Left nostril
5X
5X
2
10X
Squeeze
3
3 Drops
4
10 min
Wait 10 mins
5
C
COV
Flu B
Flu A
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CorDx
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2 Test cassettes
2 Swabs
2 Tubes with sample processing solution
1 Quick reference instructions
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CorDx
Tyfast
Flu A/B & COVID-19
At Home Multiplex Rapid Test
Press here to open
3 in 1
Fast Results
10 mins
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
2 Tests
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Flu A/B & COVID-19
At Home Multiplex Rapid Test
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9540 Waples St. #C
San Diego, CA 92121
Tel: +1-858-333-1122
Email: Info@CorDx.com
www.CorDx.com


CorDx
V02
CorDx
Tyfast
Flu A/B & COVID-19
1
Right nostril
Left nostril
5X
5X
2
10X
Squeeze
3
3 Drops
4
10 min
Wait 10 mins
5
C
COV
Flu B
Flu A
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For results interpretation, please refer to the instructions for use or visit CorDx.com
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Pre-made hole for tube
CorDx
COMPONENTS
4 Test cassettes
4 Swabs
4 Tubes with sample processing solution
1 Quick reference instructions
MATERIALS REQUIRED BUT NOT PROVIDED
Timer or clock
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CorDx
Tyfast
Flu A/B & COVID-19
At Home Multiplex Rapid Test
Nasal Swab
Multi Target
Press here to open
3 in 1
Fast Results
10 mins
For in vitro diagnostic use
For Emergency Use Authorization (EUA) only
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CorDx
V02
CorDx
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Flu A/B & COVID-19
1
Right nostril
Left nostril
5X
5X
2
10X
Squeeze
3
3 Drops
4
10 min
Wait 10 mins
5
C
COV
Flu B
Flu A
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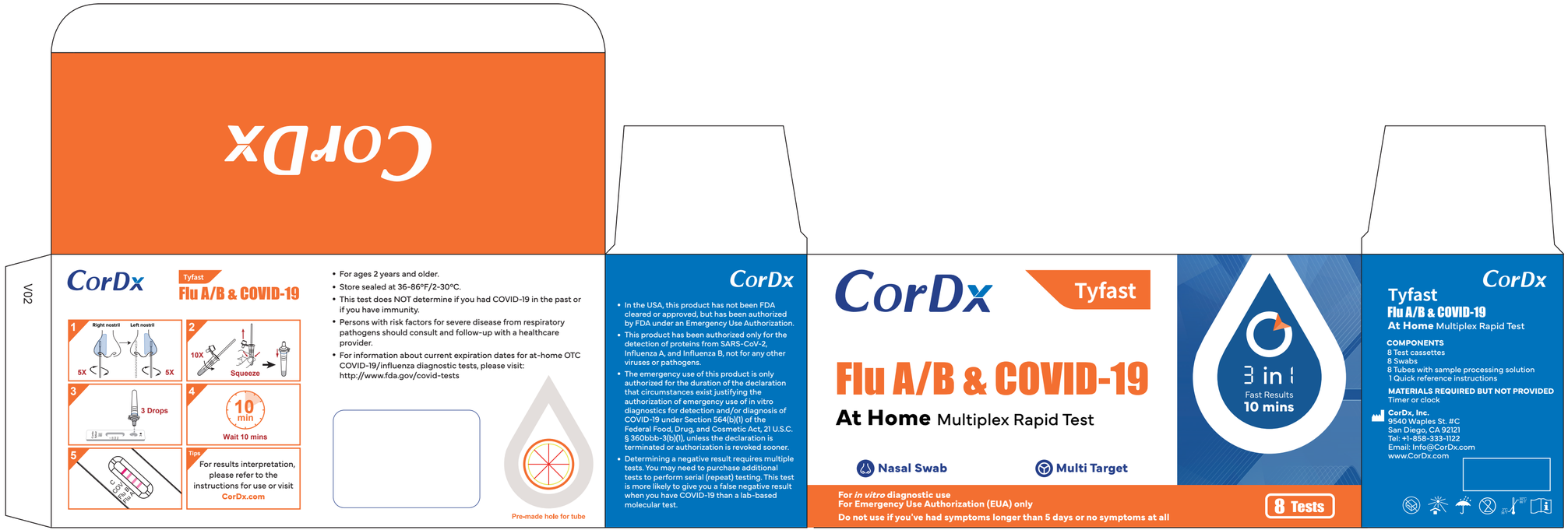
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CorDx

V02

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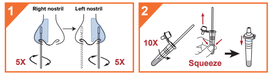

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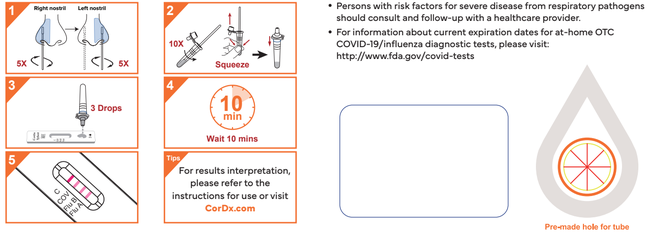

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