QUICK REFERENCE INSTRUCTIONS At-Home OTC
For technical support, please email support@cordx.com

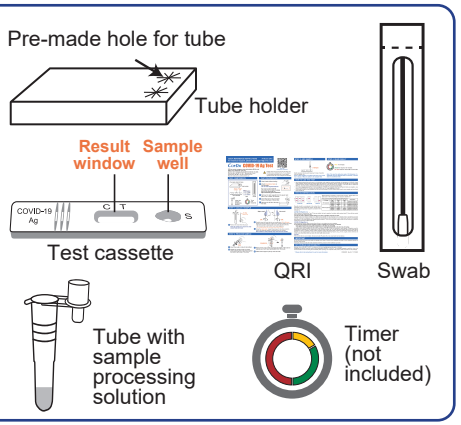
CorDx COVID-19 Ag Test

Scan for instructions and timer

FOR use under emergency use authorization (EUA) only.
FOR in vitro diagnostic use only.
Children of 2-13 years old should be tested by an adult.
Store the kit at 36~86˚F/2~30˚C. Bring the kit to room temperature (59~86˚F/15~30˚C) before the test.
Read the instructions carefully before use.

A false result may occur if all the test steps are not followed as indicated below. If you skipped or incorrectly performed one or more steps, repeat the test with a new sample and cassette.

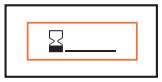
TEST COMPONENTS



TEST PREPARATION

A Wash hands before testing.

B Check **Expiration Date** on the package.
Do not use expired test kit!

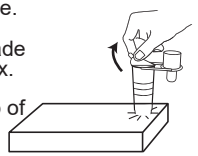


For most current shelf-life information of this test lot, please refer to the following link:
http://www.fda.gov/covid-tests

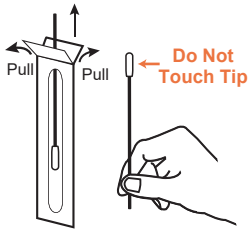
C Remove the test cassette from the pouch and place it on a clean, flat surface.

D Insert the tube in the pre-made hole on the back of the kit box.

E Remove the foil from the top of the tube.

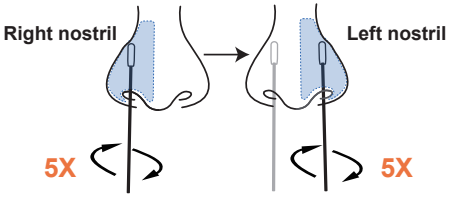


STEP 1: COLLECT SAMPLE



A Remove the swab from the pouch.

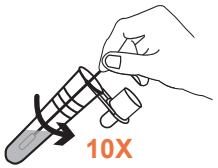
Note: Be careful not to touch the swab tip (soft end) with hand.



B Carefully insert the swab tip into one nostril about **1/2** to **3/4 inch.** 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.

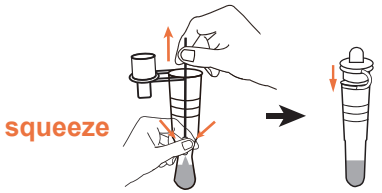
C Using the **same swab,** repeat this process for the other nostril to ensure an adequate sample is collected from both nostrils.
Note: Failure to swab properly may cause incorrect results.

STEP 2: PROCESS SAMPLE



A Insert the swab in tube to the bottom.

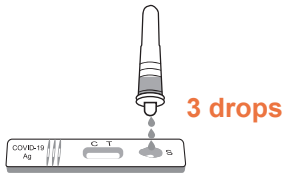
B Rotate the swab at least 10 times while pressing the swab head against the bottom and side of the tube.



C Remove the swab while squeezing the sides of the tube to express as much liquid as possible from the swab.

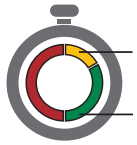
D Attach the dropper tip firmly onto the tube.

STEP 3: ADD SAMPLE



Gently squeeze the tube and dispense 3 drops of solution into the sample well.
Note: A false negative or invalid result may occur if less than 3 drops of fluid are added to the Sample Well.

STEP 4: READ RESULT



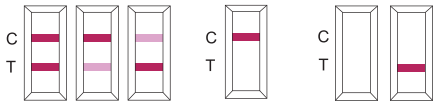
Wait 10 minutes
Read the result at 10 minutes
Do not read the result after 30 minutes

Note: The result is valid when read at 10-30minutes. If a POSITIVE result is obtained within 10 minutes, it should also be considered valid.

HOW TO USE THIS TEST

- Serial testing should be performed in all individuals with negative results; individuals with symptoms of COVID-19 and initial negative results should be tested again after 48 hours. Individuals without symptoms of COVID-19, and with initial negative results, should be tested again after 48 hours and, if the 2nd test is also negative, a 3rd time after an additional 48 hours. You may need to purchase additional tests to perform this serial (repeat) testing.
- If you test 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 positive, then proteins from the virus that causes COVID-19 have been found in your sample and you likely have COVID-19.

TEST INTERPRETATION



Repeat testing is needed to improve test accuracy. Please follow the table below when interpreting test results for COVID-19.

Status on first day of Testing	First Result **Day 1**	Second Result **Day 3**	Third Result **Day 5**	Interpretation
With Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	N/A	Negative for COVID-19
Without Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	Positive	Positive for COVID-19
	Negative	Negative	Negative	Negative for COVID-19

Results should be considered in the context of an individual's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19.

COVID-19 Positive (+)

If the Control (C) line and the Test (T) line are visible, the test is positive. Any faint visible colored test (T) line with the control line (C) should be read as positive.
You do not need to perform repeat testing if you have a positive result at any time.
A positive test result means that the virus that causes COVID-19 was detected in your sample and it is very likely you have COVID-19 and are contagious. Please contact your doctor/primary care physician or your local health authority immediately and adhere to the local guidelines regarding self-isolation. There is a very small chance that this test can give a positive result that is incorrect (a false positive).

COVID-19 Negative (-)

If the Control (C) line is visible, but the Test (T) line is not visible, 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 have symptoms on the first day of testing.**
- **Test 2 more times at least 48 hours apart if you do not have symptoms on the first day of testing.**

A negative test result indicates that the virus that causes COVID-19 was not detected in your sample. A negative result is presumptive, meaning it is not certain that you do not have COVID-19. You may still have COVID-19 and you may still be contagious. There is a higher chance of false negative results with antigen tests compared to laboratory-based tests such as PCR. If you test negative and continue to experience COVID-19-like symptoms, (e.g., fever, cough, and/or shortness of breath) you should seek follow up care with your health care provider.

Invalid

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

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.

KIT STORAGE AND STABILITY

Storage: store at 36~86˚F/2~30˚C in a place out of direct sunlight and out of reach of children.
Reagents and devices 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 testing kit immediately after opening. The expiration date (Use-by date) is printed on the package.

** Please refer to the instructions for use for more information*

PI2022001 Rev.05, 11/17/2022

INTENDED USE

The CorDx COVID-19 Ag Test is a lateral flow immunoassay device intended for the qualitative detection of nucleocapsid protein antigen from the SARS-CoV-2 virus.

This test is authorized for non-prescription home use with self-collected anterior nasal (nares) swab samples from individuals aged 14 years or older or adult collected anterior nasal (nares) swab samples from individuals aged two years or older. This test is authorized for individuals with symptoms of COVID-19 within the first 7 days of symptom onset when tested at least twice over three days with at least 48 hours between tests, and for individuals without symptoms or other epidemiological reasons to suspect COVID-19, when tested at least three times over five days with at least 48 hours between tests.

The CorDx COVID-19 Ag Test does not differentiate between SARS-CoV and SARS-CoV-2.

Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen, which is generally detectable in anterior nasal (nares) swab specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with past medical 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 definite cause of disease. Individuals who test positive with the CorDx COVID-19 Ag 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 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control measures such as isolating from others and wearing masks. Negative results should be considered in the context of an individual's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19.

Individuals who test negative and continue to experience COVID-19 like symptoms of fever, cough and/or shortness of breath may still have SARS-CoV-2 infection and should seek follow up care with their physician or healthcare provider.

Individuals should provide all results obtained with this product to their healthcare provider for public health reporting and to receive appropriate medical care. All healthcare providers will report all test results they receive from individuals who use the authorized product to relevant public health authorities in accordance with local, state, and federal requirements using appropriate LOINC and SNOMED codes, as defined by the Laboratory In Vitro Diagnostics (LIVD) Test Code Mapping for SARS-CoV-2 Tests provided by CDC.

The CorDx COVID-19 Ag Test is intended for non-prescription self-use and/or as applicable an adult lay user testing another person 2 years of age or older in a non-laboratory setting. The CorDx COVID-19 Ag Test is only for use under the Food and Drug Administration's Emergency Use Authorization. This product has not been FDA cleared or approved.

WARNINGS, PRECAUTIONS AND SAFETY INFORMATION

- Read all instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate test results.
- If you skipped or incorrectly performed one or more steps, repeat the test with a new sample and cassette.
- 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 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 negative results at least twice over three days (with 48 hours between tests) for symptomatic individuals and three times over five days (with at least 48 hours between tests) for asymptomatic individuals. You may need to purchase additional tests to perform this serial (repeat) testing.
- If you have had symptoms longer than 7 days you should consider testing at least three times over five days with at least 48 hours between tests.
- 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 kit past its expiration date.
- Do not touch the swab tip.
- Once opened, the test card should be used within 60 minutes.
- 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.
- If uncertain how to proceed, contact Technical Assistance at ***support@cordx.com.***
- This product is only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.
- When collecting an anterior nasal swab sample, only use the swab provided in the kit.
- Inadequate or inappropriate specimen collection, may yield false negative test results.
- Testing should be performed in an area with good lighting.
- Dispose of all materials in household waste.
- Wash hands thoroughly or use hand sanitizer before and after the test.
- 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/COVID-19***
- Keep testing kit and kit components away from children and pets before and after use. Avoid contact with your 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.***

Chemical	Harms (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)	0.05%

LIMITATIONS

- There is a higher chance of false negative results with antigen tests than with laboratory-based molecular tests due to the sensitivity of the test technology. This means that there is a higher chance this test will give a false negative result in an individual with COVID-19 as compared to a molecular test, especially in samples with low viral load.
- The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between March 2022 and May 2022. 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 SARSCoV-2 and their prevalence, which change over time.
- All COVID-19 antigen test negative results are presumptive and confirmation with a molecular assay may be necessary. If you 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 a healthcare provider.
- If the test is positive, then proteins from the virus that causes COVID-19 have been found in the sample and you likely have COVID-19.
- This test is read visually and has not been validated for use by those with impaired vision or color-impaired vision. Incorrect test results may occur if a specimen is incorrectly collected or handled.

FREQUENTLY ASKED QUESTIONS

1) WHAT ARE THE KNOWN AND POTENTIAL RISKS AND BENEFITS OF THE TEST?

Potential risks include: a) Possible discomfort during sample collection. b)Possible incorrect test result (see Warnings and Result Interpretation sections for more information).

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

For more information on EUAs go here: ***https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization***

2) WHAT IS THE DIFFERENCE BETWEEN AN ANTIGEN AND MOLECULAR TEST?

There are different kinds of tests for the SARS-CoV-2 virus that causes COVID-19. Molecular tests detect genetic material from the virus. Antigen tests, such as the CorDx COVID-19 Ag 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.

3) HOW ACCURATE IS THIS TEST?

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)

https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-antigen-diagnostic-tests-sars-cov-2

4) WHAT IF I HAVE A POSITIVE TEST RESULT?

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.

5) WHAT IF I HAVE A NEGATIVE TEST RESULT?

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.

6) WHAT DOES AN INVALID TEST RESULT MEAN?

An invalid result means the test was not able to tell if you have COVID-19 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.

INDEX OF SYMBOLS

	Do not re-use		Use-by date (Expiration date)	REF	Catalogue number
LOT	Batch code		Consult instructions for use		Keep dry
20°C 36°F 30°C 86°F	Store at 36~86˚F/2~30˚C		Manufacturer		Keep away from sunlight
	Caution		Do not use if package is damaged and consult instructions for use		

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

Manufacturing sites:
CorDx, Inc.
8940 Kenamar Dr, San Diego, CA 92121,
3719 North Peachtree Rd, Suite 200, Chamblee, GA 30341
Core Technology Co., Ltd.
No.30, Area 9, Douda Avenue, Fangshan District, Beijing 102433, China

69mm

129mm

CorDx

· Commitment

COVID-19 Ag Test

At Home OTC

For Use under FDA Emergency Use Authorization (EUA) only

1 Test

IVD

Use within 1 hour of opening

Refer to the outer packaging of the product for the LOT (Batch code) and (Expiration date).
For most current shelf-life information of this test lot, please refer to the following link:
http://www.fda.gov/covid-tests

CorDx

CorDx COVID-19 Ag Test

The CorDx COVID-19 Ag Test is intended for the qualitative detection of SARS-COV-2 nucleocapsid protein antigen in anterior nasal (nares) swab samples.

Read the QRI and instructions fully and carefully before performing the procedure.

- This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.
- 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.

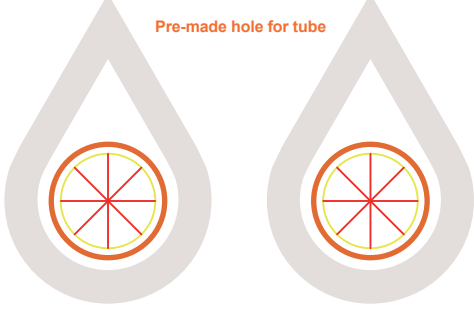
DO USE

- ✓ As an aid in the **diagnosis of current COVID-19**
- ✓ If you are concerned that you have been exposed to COVID-19
- ✓ **With** or **without** symptoms

DO NOT USE

- ✗ On anyone **under 2 years** of age
- ✗ If you are prone to nose-bleeds
- ✗ If you have had a facial or head injury/surgery in the last 6 months

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



UPC

UDI

Scan for instructions and timer

IVD

Store the kit at 36~86℉/2~30℃.

Use within 1 hour after opening the foil test cassette pouch

LOT

REF CO291-2

For most current shelf-life information of this test lot, please refer to the following link: *http://www.fda.gov/covid-tests*

- In the USA, this product has not been FDA cleared or approved, but has been authorized by FDA under an EUA.
- 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.

CorDx

· Commitment

COVID-19 Ag Test

At Home OTC

FOR technical support, please call: +1 (858)333-1122

For Use under FDA Emergency Use Authorization (EUA) only

2 Tests

Manufacturing sites:
CorDx, Inc:
8940 Kenamar Dr, San Diego, CA 92121,
3719 North Peachtree Rd. Suite 200, Chamblee, GA 30341
Core Technology Co., Ltd
No.30, Area 9, Douda Avenue, Fangshan District, Beijing 102433, China

CorDx, Inc.
9540 Waples St Unit C, San Diego, CA 92121
Web: CorDx.com
Email: info@CorDx.com

FOR in vitro diagnostic use only

TEST COMPONENTS:
2 Test cassettes
2 Swabs
2 Tubes with sample processing solution
2 Tube holders (back of box)
1 Instructions for use

165mm

76mm

18mm

CorDx

CorDx COVID-19 Ag Test

The CorDx COVID-19 Ag Test is intended for the qualitative detection of SARS-COV-2 nucleocapsid protein antigen in anterior nasal (nares) swab samples.

Read the QRI and instructions fully and carefully before performing the procedure.

- This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.
- 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.

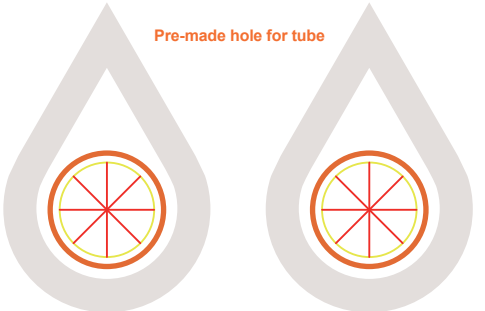
DO USE

- ✓ As an aid in the **diagnosis of current COVID-19**
- ✓ If you are concerned that you have been exposed to COVID-19
- ✓ **With** or **without** symptoms

DO NOT USE

- ✕ On anyone **under 2 years** of age
- ✕ If you are prone to nose-bleeds
- ✕ If you have had a facial or head injury/surgery in the last 6 months

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



UPC | UDI

Scan for instructions and timer

IVD

Store the kit at 36~86℉/2~30℃.

Use within 1 hour after opening the foil test cassette pouch

- In the USA, this product has not been FDA cleared or approved, but has been authorized by FDA under an EUA.
- 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.

REF CO291-4

LOT

For most current shelf-life information of this test lot, please refer to the following link: *http://www.fda.gov/covid-tests*

CorDx

· Commitment

COVID-19 Ag Test

At Home OTC

10 mins
Fast Results

FOR technical support, please call: +1 (858)333-1122

For Use under FDA Emergency Use Authorization (EUA) only

4 Tests

Manufacturing sites:
CorDx, Inc.
8940 Kenamar Dr, San Diego, CA 92121,
3719 North Peachtree Rd, Suite 200, Chamblee, GA 30341
Core Technology Co., Ltd.
No 30, Area 9, Douda Avenue, Fangshan District,
Beijing 102433, China

CorDx, Inc.
9540 Waples St Unit C, San Diego, CA 92121
Web: CorDx.com
Email: info@CorDx.com
FOR in vitro diagnostic use only

TEST COMPONENTS:
4 Test cassettes
4 Swabs
4 Tubes with sample processing solution
2 Tube holders (back of box)
1 Instructions for use

165mm

76mm

30mm

CorDx

CorDx COVID-19 Ag Test

The CorDx COVID-19 Ag Test is intended for the qualitative detection of SARS-COV-2 nucleocapsid protein antigen in anterior nasal (nares) swab samples.

Read the QRI and instructions fully and carefully before performing the procedure.

- This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.
- 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.

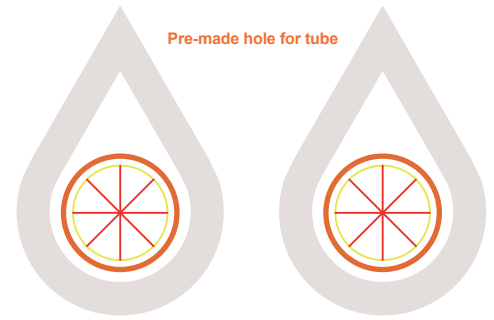
DO USE

- ✓ As an aid in the **diagnosis of current COVID-19**
- ✓ If you are concerned that you have been exposed to COVID-19
- ✓ **With** or **without** symptoms

DO NOT USE

- ✗ On anyone **under 2 years** of age
- ✗ If you are prone to nose-bleeds
- ✗ If you have had a facial or head injury/surgery in the last 6 months

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



UPC

UDI

Scan for instructions and timer

Store the kit at 36~86℉/2~30℃.

Use within 1 hour after opening the foil test cassette pouch

- In the USA, this product has not been FDA cleared or approved, but has been authorized by FDA under an EUA.
- 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.

For most current shelf-life information of this test lot, please refer to the following link: *http://www.fda.gov/covid-tests*

REF CO291-5

LOT

CorDx

· Commitment

COVID-19 Ag Test

At Home OTC

10 mins
Fast Results

FOR technical support, please call: +1 (858)333-1122

For Use under FDA Emergency Use Authorization (EUA) only

5 Tests

Manufacturing sites:
CorDx, Inc.
8940 Kenamar Dr, San Diego, CA 92121
3719 North Peachtree Rd, Suite 200, Chamblee, GA 30341
Core Technology Co., Ltd.
No.30, Area 9, Douda Avenue, Fangshan District,
Beijing 102433, China

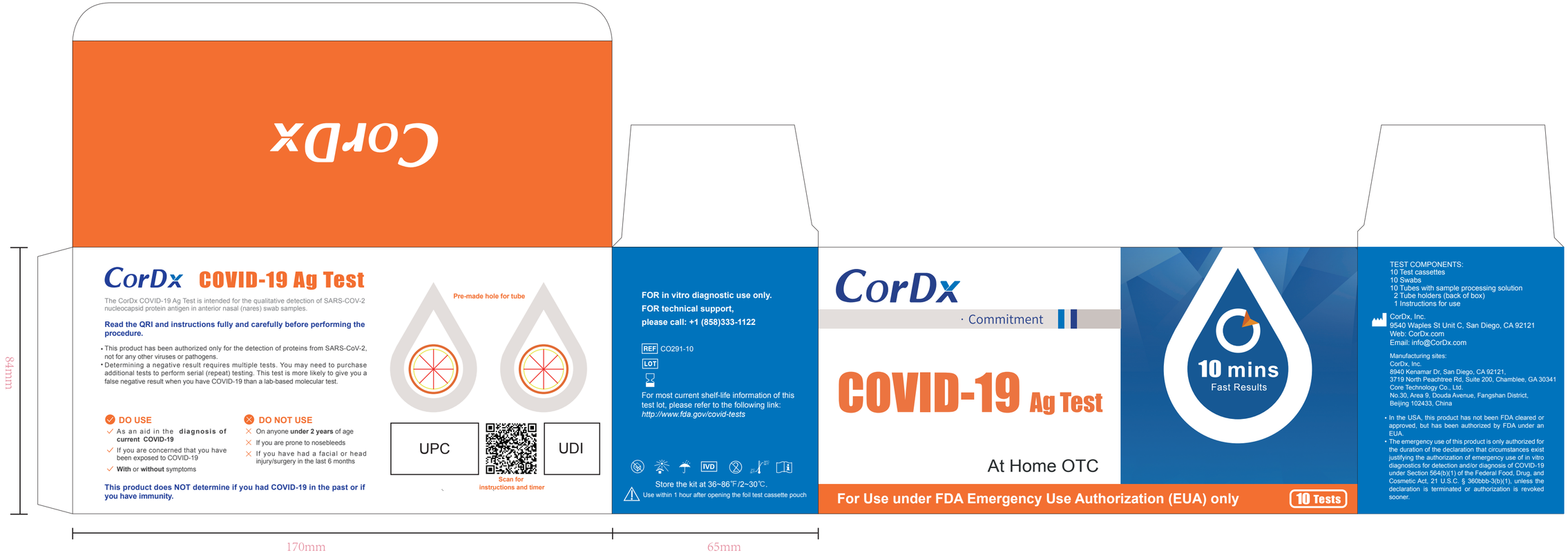
CorDx, Inc.
9540 Waples St Unit C, San Diego, CA 92121
Web: CorDx.com
Email: info@CorDx.com

FOR in vitro diagnostic use only

TEST COMPONENTS:
5 Test cassettes
5 Swabs
5 Tubes with sample processing solution
2 Tube holders (back of box)
1 Instructions for use

76mm

36mm


CorDx
CorDx COVID-19 Ag Test
The CorDx COVID-19 Ag Test is intended for the qualitative detection of SARS-COV-2 nucleocapsid protein antigen in anterior nasal (nares) swab samples.
Read the QRI and instructions fully and carefully before performing the procedure.
• This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.
• 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.
DO USE
As an aid in the diagnosis of current COVID-19
If you are concerned that you have been exposed to COVID-19
With or without symptoms
DO NOT USE
On anyone under 2 years of age
If you are prone to nosebleeds
If you have had a facial or head injury/surgery in the last 6 months
This product does NOT determine if you had COVID-19 in the past or if you have immunity.
Pre-made hole for tube
UPC
UDI
Scan for instructions and timer
FOR in vitro diagnostic use only.
FOR technical support,
please call: +1 (858)333-1122
REF CO291-10
LOT
For most current shelf-life information of this test lot, please refer to the following link:
http://www.fda.gov/covid-tests
Store the kit at 36~86°F /2~30℃.
Use within 1 hour after opening the foil test cassette pouch
CorDx
· Commitment
COVID-19 Ag Test
At Home OTC
10 mins
Fast Results
For Use under FDA Emergency Use Authorization (EUA) only
10 Tests
TEST COMPONENTS:
10 Test cassettes
10 Swabs
10 Tubes with sample processing solution
2 Tube holders (back of box)
1 Instructions for use
CorDx, Inc.
9540 Waples St Unit C, San Diego, CA 92121
Web: CorDx.com
Email: info@CorDx.com
Manufacturing sites:
CorDx, Inc.
8940 Kenamar Dr, San Diego, CA 92121,
3719 North Peachtree Rd, Suite 200, Chamblee, GA 30341
Core Technology Co., Ltd.
No.30, Area 9, Douda Avenue, Fangshan District,
Beijing 102433, China
• In the USA, this product has not been FDA cleared or approved, but has been authorized by FDA under an EUA.
• 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.
84mm
170mm
65mm

At Home OTC

COVID-19 Ag Test

CorDx · Commitment

CorDx COVID-19 Ag Test

The CorDx COVID-19 Ag Test is intended for the qualitative detection of SARS-COV-2 nucleocapsid protein antigen in anterior nasal (nares) swab samples.

Read the QRI and instructions fully and carefully before performing the procedure.

- This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.
- 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.

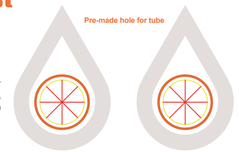
DO USE

- As an aid in the **diagnosis of current COVID-19**
- If you are concerned that you have been exposed to COVID-19
- **With** or **without** symptoms

DO NOT USE

- On anyone **under 2 years** of age
- If you are prone to nosebleeds
- If you have had a facial or head injury/surgery in the last 6 months

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



Scan for instructions and timer

UDI

CorDx

FOR in vitro diagnostic use only.
FOR technical support,
please call: +1 (858)333-1122

UPC

REF CO291-20

LOT

For most current shelf-life information of this test lot, please refer to the following link:
http://www.fda.gov/covid-tests

IVD

Store the kit at 36~86℉/2~30℃.

Use within 1 hour after opening the foil test cassette pouch

10 mins
Fast Results

For Use under FDA Emergency Use Authorization (EUA) only

20 Tests

TEST COMPONENTS:
20 Test cassettes
20 Swabs
20 Tubes with sample processing solution
2 Tube holders (Back of box)
1 Instructions for Use

CorDx, Inc.
9540 Waples St Unit C, San Diego, CA 92121
Web: CorDx.com
Email: info@CorDx.com

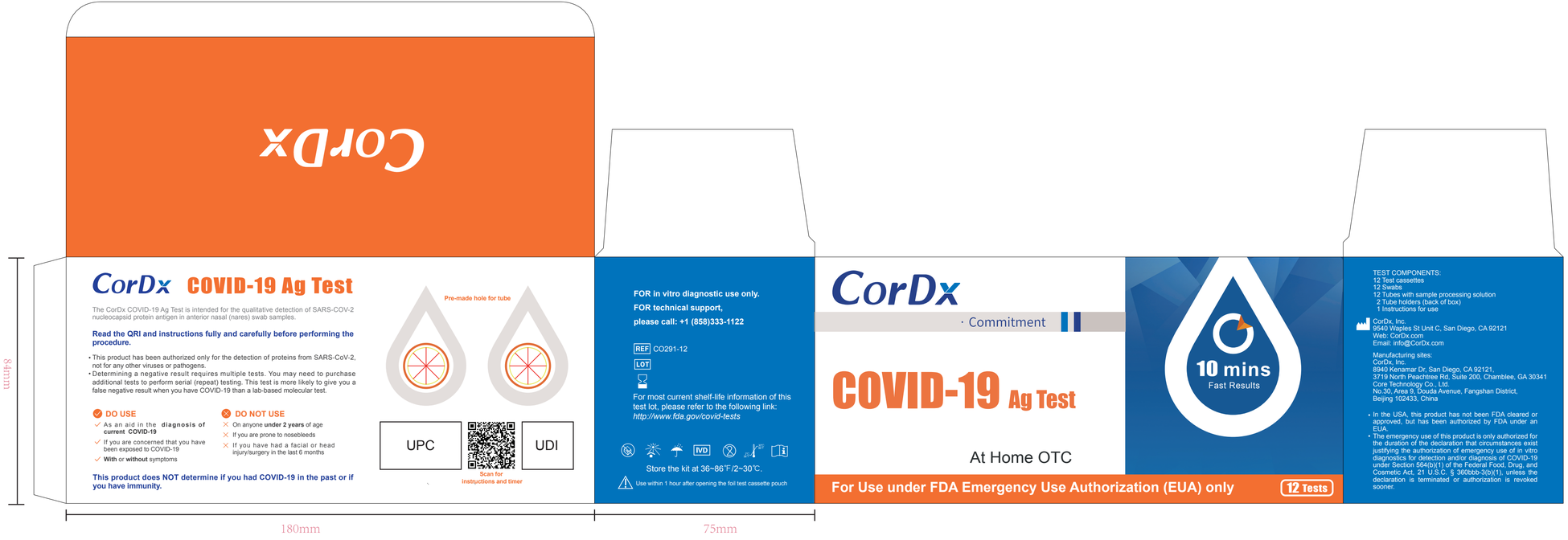
- In the USA, this product has not been FDA cleared or approved, but has been authorized by FDA under an EUA.
- The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection 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.

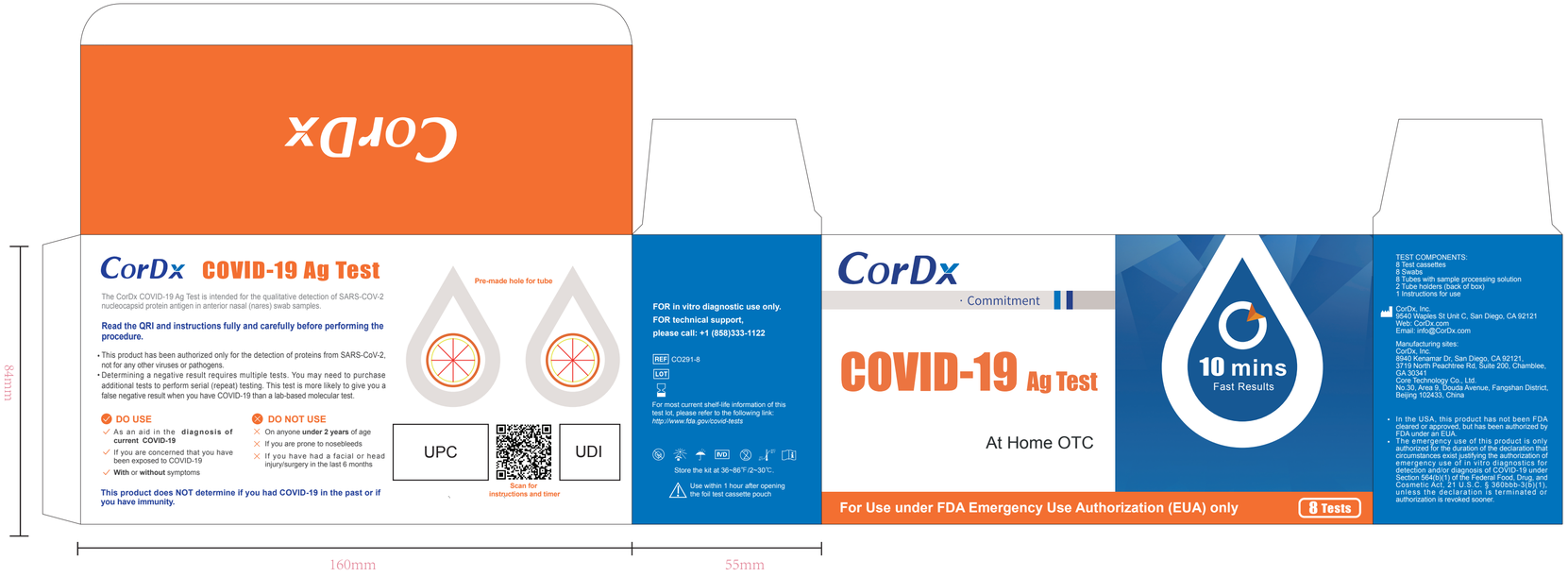
Manufacturing sites:
CorDx, Inc.
8940 Kenamar Dr, San Diego, CA 92121,
3719 North Peachtree Rd. Suite 200, Chamblee, GA 30341
Core Technology Co., Ltd.
No.30, Area 9, Douda Avenue, Fangshan District, Beijing 102433, China

84mm

200mm

132mm


CorDx
CorDx COVID-19 Ag Test
The CorDx COVID-19 Ag Test is intended for the qualitative detection of SARS-COV-2 nucleocapsid protein antigen in anterior nasal (nares) swab samples.
Read the QRI and instructions fully and carefully before performing the procedure.
• This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.
• 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.
DO USE
As an aid in the diagnosis of current COVID-19
If you are concerned that you have been exposed to COVID-19
With or without symptoms
DO NOT USE
On anyone under 2 years of age
If you are prone to nosebleeds
If you have had a facial or head injury/surgery in the last 6 months
This product does NOT determine if you had COVID-19 in the past or if you have immunity.
Pre-made hole for tube
UPC
UDI
Scan for instructions and timer
FOR in vitro diagnostic use only.
FOR technical support,
please call: +1 (858)333-1122
REF CO291-12
LOT
For most current shelf-life information of this test lot, please refer to the following link:
http://www.fda.gov/covid-tests
IVD
Store the kit at 36~86℉/2~30℃.
Use within 1 hour after opening the foil test cassette pouch
CorDx
· Commitment
COVID-19 Ag Test
At Home OTC
For Use under FDA Emergency Use Authorization (EUA) only
12 Tests
10 mins
Fast Results
TEST COMPONENTS:
12 Test cassettes
12 Swabs
12 Tubes with sample processing solution
2 Tube holders (back of box)
1 Instructions for use
CorDx, Inc.
9540 Waples St Unit C, San Diego, CA 92121
Web: CorDx.com
Email: info@CorDx.com
Manufacturing sites:
CorDx, Inc.
8940 Kenamar Dr, San Diego, CA 92121,
3719 North Peachtree Rd, Suite 200, Chamblee, GA 30341
Core Technology Co., Ltd.
No.30, Area 9, Douda Avenue, Fangshan District,
Beijing 102433, China
• In the USA, this product has not been FDA cleared or approved, but has been authorized by FDA under an EUA.
• 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.
84mm
180mm
75mm


CorDx
CorDx COVID-19 Ag Test
The CorDx COVID-19 Ag Test is intended for the qualitative detection of SARS-COV-2 nucleocapsid protein antigen in anterior nasal (nares) swab samples.
Read the QRI and instructions fully and carefully before performing the procedure.
• This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.
• 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.
DO USE
As an aid in the diagnosis of current COVID-19
If you are concerned that you have been exposed to COVID-19
With or without symptoms
DO NOT USE
On anyone under 2 years of age
If you are prone to nosebleeds
If you have had a facial or head injury/surgery in the last 6 months
This product does NOT determine if you had COVID-19 in the past or if you have immunity.
Pre-made hole for tube
UPC
UDI
Scan for instructions and timer
FOR in vitro diagnostic use only.
FOR technical support, please call: +1 (858)333-1122
REF CO291-8
LOT
For most current shelf-life information of this test lot, please refer to the following link:
http://www.fda.gov/covid-tests
Store the kit at 36~86℉/2~30℃.
Use within 1 hour after opening the foil test cassette pouch
CorDx
· Commitment
COVID-19 Ag Test
At Home OTC
10 mins
Fast Results
For Use under FDA Emergency Use Authorization (EUA) only
8 Tests
TEST COMPONENTS:
8 Test cassettes
8 Swabs
8 Tubes with sample processing solution
2 Tube holders (back of box)
1 Instructions for use
CorDx, Inc.
9540 Waples St Unit C, San Diego, CA 92121
Web: CorDx.com
Email: info@CorDx.com
Manufacturing sites:
CorDx, Inc.
8940 Kenamar Dr, San Diego, CA 92121,
3719 North Peachtree Rd, Suite 200, Chamblee, GA 30341
Core Technology Co., Ltd.
No.30, Area 9, Douda Avenue, Fangshan District, Beijing 102433, China
In the USA, this product has not been FDA cleared or approved, but has been authorized by FDA under an EUA.
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.
84mm
160mm
55mm