**COVID-19 Ag Test**

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.

**Test Components**

- **Pre-made hole for tube**
- **Tube holder**
- **Result Sample window**
- **Test cassette**
- **QRI**
- **Swab**

**Preparation**

A. Wash hands before testing.

B. Check Expiration Date on the package.

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.

**Add Sample**

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

**Interpretation**

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

<table>
<thead>
<tr>
<th>Status on 1st day of Testing</th>
<th>1st Result Day 1</th>
<th>2nd Result Day 3</th>
<th>3rd Result Day 5</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>With Symptoms</td>
<td></td>
<td></td>
<td></td>
<td>Positive, Negative, N/A</td>
</tr>
<tr>
<td>Positive</td>
<td>Positive</td>
<td>Negative</td>
<td>Negative, Positive for COVID-19</td>
<td></td>
</tr>
<tr>
<td>Negative</td>
<td>Negative</td>
<td>Negative</td>
<td>Negative, Positive, Positive for COVID-19</td>
<td></td>
</tr>
<tr>
<td>N/A</td>
<td>Positive</td>
<td>N/A</td>
<td>N/A</td>
<td>Positive, Negative, N/A</td>
</tr>
<tr>
<td>Without Symptoms</td>
<td></td>
<td></td>
<td></td>
<td>Positive, Negative, N/A</td>
</tr>
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<td>Positive</td>
<td>N/A</td>
<td>N/A</td>
<td>Positive, Negative, N/A</td>
</tr>
<tr>
<td>Negative</td>
<td>Negative</td>
<td>N/A</td>
<td>N/A</td>
<td>Positive, Negative, Positive, Positive for COVID-19</td>
</tr>
<tr>
<td>N/A</td>
<td>Positive</td>
<td>N/A</td>
<td>N/A</td>
<td>Positive, Negative, N/A</td>
</tr>
</tbody>
</table>

**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.
- 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.

**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.

**Storage**

Store at 36–86°F (2–30°C) in a place out of direct sunlight and out of reach of children.

Re-use of test kit 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*
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 (nasal) 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 18 hour 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 (nases) swab specimens during the 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.

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 (EUA) 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. § 360bb-b (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 (repeating) 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.
• Inappropriate or inappropriate specimen collection may yield false negative test results.
• Testing should be performed in a area with good lighting.
• Dispose of all materials in household waste.
• Wash hands thoroughly with 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

3) 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 of getting a false negative result when you have COVID-19 than a molecular test would.

4) HOW CAN I SAFE TEST IF I AM NOT SICK?
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 infection 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 (fIU).


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 POSITIVE TEST RESULT?
A positive result does not rule out other viral infections such as bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. 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?
The test was invalid if it tells 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
Manufacturer
Consult instructions for use
Catalogue number
Keep dry
Keep away from sunlight
Cautions
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 Kenmore Dr, San Diego, CA 92121,
3719 North Peachtree Rd, Suite 200, Chamblee, GA 30341
Core Technology Co., Ltd.
No.30, Area 9, Doula Avenue, Fangshan District, Beijing 102433, China

LIMITATIONS
• There is a higher chance of false negative results with antigen tests than with laboratory-based molecular tests due to the sensitivity of antigen 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 27, 2020 and May 2022. The clinical performance 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, and therefore clinical correlations may not be predictive.
• 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, nor necessarily should you 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

Chemical Name (GHS Code) for each ingredient
Concentrations
Triton X-100
Harmful if swallowed (H302) Causes skin irritation (H315) Causes serious eye damage (H319)
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 (H311)
0.05%
Fast Results

1 Test

At Home OTC

COVID-19 Ag Test

10 mins

Fast Results

For Use under FDA Emergency Use Authorization (EUA) only

Refer to the outer packaging of the product for the (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

Use within 1 hour of opening
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.

Pre-made hole for tube

Scan for instructions and timer

UPC

UDI

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

For Use under FDA Emergency Use Authorization (EUA) only

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.

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

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- 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.

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

**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 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](http://www.fda.gov/covid-tests)

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

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

Core Technology Co., Ltd.
No.30, Area 9, Douda Avenue, Fangshan District, Beijing 102433, China

**FOR in vitro diagnostic use only**

**Use within 1 hour after opening the foil test cassette pouch**

**Store the kit at 36~86°F/2~30°C.**

Use within 1 hour after opening the foil test cassette pouch.
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.

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For Use under FDA Emergency Use Authorization (EUA) only

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

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

CO291-5
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.

- The product has been authorized only for the detection of products from SARS-CoV-2, not to assist in diagnosis of other diseases.
- You must test only if you have symptoms.
- The test does NOT determine if you had COVID-19 in the past or if you have immunity.

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

FOR in vitro diagnostic use only.

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

Store the kit at 36~86 ℉/2~30 ℃.

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 in a partner serum in order to confirm. This test is not recommended as a replacement for recommended health care.

Use within 1 hour after opening the foil test cassette pouch.

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

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 USE
- On anyone 2 years of age and older
- If you have a fever

DO NOT USE
- On anyone under 2 years of age
- With or without symptoms

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

For Use under FDA Emergency Use Authorization (EUA) only

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

This test is more likely to give you a false negative result when you have COVID-19 than a lab-based molecular test.

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.

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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.

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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 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

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

Store the kit at 36~86 ℉/2~30 ℃.

12 Tests At Home OTC COVID-19 Ag Test

Pre-made hole for tube

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.

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

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

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.

Use within 1 hour after opening the foil test cassette pouch.

Scan for instructions and timer

UDIUPC
CO291-12

FOR in vitro diagnostic use only.

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

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

For Use under FDA Emergency Use Authorization (EUA) only

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 USE

On anyone under 2 years of age
If you have had a facial or head injury/surgery in the last 6 months
DO NOT USE
This product does NOT determine if you had COVID-19 in the past or if you have immunity.

Store the kit at 36~86°F/2~30°C.

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

Pre-made hole for tube
Use within 1 hour after opening the foil test cassette pouch

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

For Use under FDA Emergency Use Authorization (EUA) only

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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 SARS-CoV-2 and is not intended to be used for the diagnosis of 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.

Scan for instructions and timer
UDIUPC
CO291-8

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

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

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 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

DO NOT USE
In case of any abnormal reactions
If use is continued beyond the time recommended in the QRI
If you are pregnant
If you have a history of high blood pressure or other heart problems
If you are over 65 years of age or have a history of heart disease
If you are under the age of 2 or have any other medical conditions
If you are using any other medications or supplements

UDIUPC
CO291-8

For use under FDA Emergency Use Authorization (EUA) only.