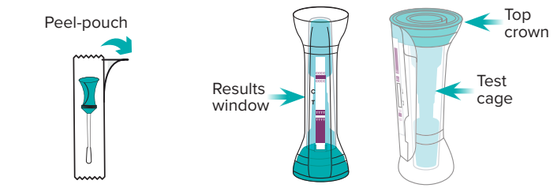
COVI-Go™

SARS-CoV-2 Ag | Self-Test

INSTRUCTIONS FOR USE

For use with anterior nasal swab specimens.
For Emergency Use Authorization (EUA) only.
In vitro diagnostic use only.

KIT CONTENTS



1 Sterile flocked nasal swab in a peel-pouch

1 Single-use, disposable test device in a notched foil pouch

Needed but not provided: clock or timer

STORAGE AND HANDLING

- Test kits must be stored at 35.6–86°F (2–30°C) until use.
- Test kits must be stored out of reach of children. Discard any expired test kits in household waste.
- Do not reuse test components.
- Do not open the test kit until you are ready to test.

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.**

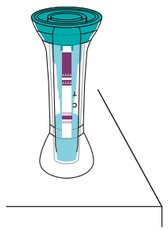
A. PREPARING FOR THE TEST

1. Read all the instructions before you start the test.
2. Check the test's expiration date . Do not use an expired test.
3. Wash your hands with soap and water for 20 seconds and dry them thoroughly, or use hand sanitizer.
4. Use a flat, level surface, (such as a table or countertop) for testing.
5. Use a timer during the test.
6. Make sure you have all the test components before you begin.
7. Bring test kit to room temperature (59-86°F /15-30°C)
8. Perform test at room temperature. Testing under conditions other than room temperature may lead to inaccurate results.

B. TAKING THE SAMPLE AND RUNNING THE TEST

1 Peel open the notched foil pouch to unwrap the test device. Ensure that the test device is intact and that there are no green beads in the desiccant package (orange beads are expected). **Do not use test if green beads are present.**

Place the test device on a **flat surface** with the top crown at the top.



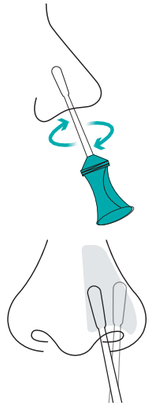
2 Blow your nose. If you are testing someone else, have them blow their nose.

3 Peel open the pouch to unwrap the swab. Make sure you hold the swab by the swab handle. Do not touch the swab tip.

4 Gently insert the entire absorbent tip of the swab into the nostril no more than ½ to ¾ inch. There is no need to go deeper.

Slowly rotate the swab in a circular motion **5 times** by firmly pressing against the inside walls of the nostril for **5 seconds**.

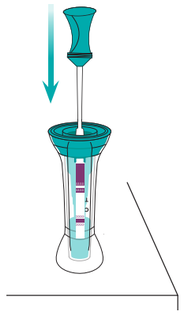
Repeat in the other nostril using the same swab.



Instructions for swabbing children: With children, you may not need to insert the swab as far into the nostril. For very young children, you may need another person to hold the child's head while swabbing.

Warning: Do not just spin the swab. Inaccurate test results may occur if the nasal swab specimen is not properly collected.

5 While the test is still on the flat surface, insert the swab into the test at the top crown, pushing the swab all the way down into the **center of the test cage.** You will hear a "click".



Continue pushing the swab all the way through until the swab handle is flush with the top of the device and you hear a second "click".

STOP

Make sure the top of the swab handle is pushed as far into the test as possible by firmly pressing the handle in with your thumb or an additional hand.

Do not proceed until you have confirmed that the swab handle is fully inserted.

6 Vigorously swing the test side to side for **4 seconds.**

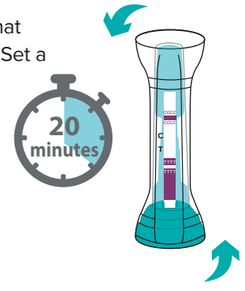
Do not attempt to shake up and down as this may cause incorrect results.

7 Set a timer for **2 minutes**. Allow the test to stand upright with the top crown up.

8 Turn the test upside down so that the top crown is at the bottom. Set a timer for **20 minutes**.

Do not lay the test on its side.

Warning: Do not read the result before 20 minutes or after 30 minutes.



C. READING THE TEST RESULTS

WARNING: Do not read the result before 20 minutes or after 30 minutes. Inaccurate test interpretations may occur.

Look at the result window and locate the letters C and T on the side of the window. A pink/purple line should always appear at the C position; this is a control line and signals that the test is working properly.

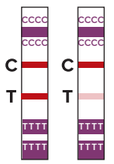
◂ Negative result

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.



◂ Positive result

If a Control (C) line and the Test (T) line are visible, the test is positive. Any faint visible pink/purple 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).

◂ Invalid result

If a control line (C) is not visible, even if the test line is visible, the result must be considered invalid.

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

INTENDED USE

The COVI-Go™ SARS-CoV-2 Ag Self-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 2 years or older. This test is authorized for individuals with symptoms of COVID-19 within the first 5 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 COVI-Go SARS-CoV-2 Ag Self-Test does not differentiate between SARS-CoV or SARSCoV-2.

Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen, which is generally detectable in anterior nasal (nares) samples 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 and the agent detected may not be the definitive cause of disease. **Individuals who test positive with the COVI-Go SARS-CoV-2 Ag Self-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 COVI-Go SARS-CoV-2 Ag Self-Test is intended for non-prescription self-use and/or as applicable, for an adult lay user testing another aged 2 years or older in a non-laboratory setting. The COVI-Go SARS-CoV-2 Ag Self-Test is only for in vitro diagnostic 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.
- 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 5 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 age 14 years and older. Children age 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 device should be used within 15 minutes.
- False results may occur if not tested at room temperature and in areas with high humidity.
- Do not read test results before 20 minutes or after 30 minutes. Results read before 20 minutes or after 30 minutes may lead to a false positive, false negative, or invalid result.
- If applicable: 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.**

Chemical Name / CAS	Hazard Catergory	Concentration
Sodium Azide Cas-No: 26628-22-8	Acute Tox. 2 (Oral), H300 Acute Tox. 1 (Dermal), H310	0.05% in final solution

- 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

SERIAL TESTING AND 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 August 2022 - November 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 SARS- CoV-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

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

Potential risks include:
- Possible discomfort during sample collection.
- Possible incorrect test result (see Warnings and Result Interpretation sections 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 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

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 COVI-Go™ SARS-CoV-2 Ag Self-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.

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), available at www.covi-go.com.

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.

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.

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.

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.

SERIAL TESTING TEST RESULT INTERPRETATION

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

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.

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

Index of Symbols

Manufacturer		Date of manufacture	
Contains sufficient for <n> tests		Catalogue number	REF
In vitro diagnostic medical device	IVD	Use-by date	
Consult instructions for use		Batch code	LOT
Store between 2-30°C / 36-86°F		Do not reuse	

Materials Provided

Components	1 Test per Box	2 Tests per Box	4 Tests per Box	100 tests per box
COVI-Go™ SARS-CoV-2 Antigen Test Device	1	2	4	100
COVI-Go™ Sterilized Swab	1	2	4	100
Quick Reference / Instructions for Use	1	1	1	1

Mologic Inc
83 Pineland Dr.
Gray Hall Suite 202
New Gloucester, ME 04260

Tel: +1-888-381-6870
Email: info@covi-go.com
www.covi-go.com

REF Number: 11619100 v13 Effective Date: 2023-2

CURTIS PACKAGING

MOLOGIC
COVID 2 test kit
21T0622D2B
114.300 x 69.850 x 187.325 mm
4+1/2 x 2+3/4 x 7+3/8 in.
.018 SBS
SEAL END

2 11/16 [68.26]
7 3/8 [187.32]
2 11/16 [68.26]
5/8 [15.87]
4 1/2 [114.3]
2 3/4 [69.85]
4 1/2 [114.3]
2 23/32 [69.06]

Glue Printside

Minor Panel
Internal Glue Area
Internal Glue Area
Minor Panel

COVI-Go™

SARS-CoV-2 Ag | **Self-Test**

Fast and easy to use COVID-19 Self-Test for infection detection

Suitable for age 2+ years

FAST RESULTS IN 20 MINUTES

EASY TESTING

For Emergency Use Authorization (EUA) only
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2 Tests

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Suitable for age 2+ years

A rapid test for the qualitative detection of COVID-19 antigens in nasal swab specimens.
For ages 13 and under, test must be administered by a caregiver.
Keep out of reach of children. The test contains small parts that may present a choking hazard.

Contents:
- 2 SARS-CoV-2 Ag Self-Test
- 2 sterile nasal sampling device
- 1 Instructions for Use

For more information, visit www.covi-go.com

- This test does NOT determine if you had COVID-19 in the past or if you have immunity.
- This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.

Items necessary to use the kit, but not provided
- Timer

For symbol glossary, refer to Instructions for Use.

Store between 36-86°F (2-30°C) until use

Mologic Inc, 83 Pineland Dr. Gray Hall, Suite 202, New Gloucester, ME 04260

HELP: Contact Mologic Technical Support at (888) 381-6870 or info@covi-go.com

Do not use if package is damaged
Consult instructions for use
LOT Lot Number
2 Single use only
Date of manufacture
IVD *In vitro diagnostic* use
REF Catalog Number
OTC Self test in vitro diagnostic device

Suitable for age 2+ years

COVID-19
ANTIGEN SELF TEST FOR INFECTION DETECTION

LOT
REF

Part# 11618101, Version 3, 02/23

FPO
5 060511 890045

COVI-Go™
Fast and easy to use COVID-19 Self-Test for infection detection

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- Determining a negative result requires multiple tests. You may need to purchase additional tests to perform serial (repeat) testing. This test is more likely to give you a false negative result when you have COVID-19 than a lab-based molecular test.
- For more information on expiration dating for COVID-19 antigen tests, please refer to http://www.fda.gov/covid-tests

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MOLOGIC
COVID 2PC KIT
20T0601A2
84.137 x 38.100 x 187.325
3+5/16 x 1+1/2 x 7+3/8
.018 SBS
06/09/2021
10+7/32 x 10+3/8
printed

Glue Printside

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Mologic Inc. 83 Pineland Dr. Gray Hall, Suite 202, New Gloucester, ME 04260
HELP: Contact Mologic Technical Support at (888) 381-6870 or info@covi-go.com

Do not use if package is damaged | Consult instructions for use | Lot Number
Date of manufacture | *In vitro diagnostic use* | Catalog Number
Single use only | Self test in vitro diagnostic device | OTC

Suitable for age 2+ years

COVID-19
ANTIGEN SELF TEST FOR INFECTION DETECTION

LOT

REF

Part# 11618100, Version 3, 02/23

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COVI-Go
Fast and easy to use COVID-19 Self-Test for infection detection

5 060511
FPO

15.875 [0.625]
84.137 [3.312]
38.100 [1.500]
84.137 [3.312]
37.306 [1.469]
259.556 [10.219]
31.750 [1.250]
187.325 [7.375]
38.100 [1.500]
263.525 [10.375]

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SARS-CoV-2 Ag | **Self-Test**

Fast and easy to use COVID-19 Self-Test for infection detection

The COVI-Go™ SARS-CoV-2 Ag Self-Test is a lateral flow immunoassay that uses antibodies to detect nucleocapsid protein from SARS-CoV-2 in anterior nasal swabs from those with symptoms of COVID-19 within the first 5 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.

Suitable for age 2+ years

A rapid test for the qualitative detection of COVID-19 antigens in nasal swab specimens. For ages 13 and under, test must be administered by a caregiver. Keep out of reach of children. The test contains small parts that may present a choking hazard.

Contents:
- 4 SARS-CoV-2 Ag Self-Test
- 4 sterile nasal sampling device
- 1 Instructions for Use

- This test does NOT determine if you had COVID-19 in the past or if you have immunity.
- This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.

Items necessary to use the kit, but not provided
- Timer

For symbol glossary, refer to Instructions for Use.

Store between 36-86°F (2-30°C) until use

Mologic Inc, 83 Pineland Dr. Gray Hall, Suite 202, New Gloucester, ME 04260

HELP: Contact Mologic Technical Support at (888) 381-6870 or info@covi-go.com

Do not use if package is damaged | Consult instructions for use | LOT Lot Number | 2 Single use only | Date of manufacture | IVD *In vitro diagnostic use*

REF Catalog Number | OTC Self test in vitro diagnostic device

Suitable for age 2+ years

COVID-19
ANTIGEN SELF TEST FOR INFECTION DETECTION

LOT

REF

Part# 11618120, Version 3, 02/23

5 060511 FPO

COVI-Go™

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SARS-CoV-2 Ag | **Self-Test**

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- 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.
- Determining a negative result requires multiple tests. You may need to purchase additional tests to perform serial (repeat) testing. This test is more likely to give you a false negative result when you have COVID-19 than a lab-based molecular test.
- For more information on expiration dating for COVID-19 antigen tests, please refer to http://www.fda.gov/covid-tests

FAST RESULTS IN 20 MINUTES

EASY TESTING

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FAST RESULTS IN 20 MINUTES

EASY TESTING

For Emergency Use Authorization (EUA) only

For *in vitro* diagnostic use

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

100 Tests

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Contents:
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- 100 sterile nasal sampling device
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Do not use if package is damaged | Consult instructions for use | LOT Lot Number | Single use only | Date of manufacture | IVD *In vitro diagnostic* use | REF Catalog Number | OTC Self test in vitro diagnostic device

Suitable for age 2+ years

COVID-19
ANTIGEN SELF TEST FOR INFECTION DETECTION

LOT

REF

Part# 11618105, Version 3, 02/23

5 060511 FPO

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