How to use this 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.

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

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

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

5. 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.

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

7. 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.

B. TAKING THE SAMPLE AND RUNNING THE TEST

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.”

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.

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 healthcare 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.
The COVI-Go SARS-CoV-2 Ag Self Test is a lateral flow immunosorbent device intended for the qualitative detection of nucleocapsid protein antigen from the SARS-CoV-2 virus.

This test is authorized for non-prescription 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 once every 3 days with at least 48 hours between tests.

The COVI-Go SARS-CoV-2 Ag Self Test does not differentiate between SARS-CoV or SARS-CoV-2. Results are for the identification of SARS-CoV-2 nucleoprotein 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 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 healthcare provider as additional testing may be necessary.

All negative results are presumptive and confirmatory 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 isolation and hospitalization of patients. 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 healthcare provider.

Individuals who obtain this product with their healthcare provider for public health reporting and to receive appropriate medical care. All healthcare providers will report all test results they receive for use by the 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 authorized 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. The FDA has authorized this test for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens. The emergency use of this product is 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)(2) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bb-b(2), unless the declaration is terminated or authorization is revoked sooner.

- Serial testing should be performed with negative results at least twice over three days (with 48 hours between tests) for asymptomatic individuals and three times over five days (with at least 48 hours between tests) for symptomatic individuals. 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. 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 aged 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 mask or other respiratory 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 test 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 or low humidity.

- Do not read test results before 20 minutes or after 30 minutes. Results need between 20 minutes or 30 minutes to may lead to a false positive, false negative, or invalid result.

- If applicable: Keep test 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 sodium azide and ethylenediaminetetraacetic acid (EDTA) with the potential to cause irritation if it comes in contact with 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.

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

- **Potential benefits 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 EUA go here: https://www.fda.gov/emergency-preparedness-and-response/ness/leg-regulatory-and-policy-framework/emergency-use-authorization

### WHAT IS THE DIFFERENCE BETWEEN AN ANTIGEN AND MOLECULAR TEST?

The 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 than when you have COVID-19 then 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 (FU), available at www.rivco.com.

### WHAT IF I HAVE A POSITIVE TEST RESULT?

A positive test result means that it is 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 antibodies 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 24 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 between tests for a total of three tests. If you have a negative result, do not rule out SARS-CoV-2 infection; you may still be infectious. This test is not intended to be used to collect a new nasal swab specimen and you should test again with a new test.

### IMPORTANT

- Do not use the 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 relevant public health authorities in accordance with local, state, and federal requirements.
Fast and easy to use COVID-19 Self-Test for infection detection

Suitable for age 2+ years

1 Test

1 Test

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.

• This product has been authorized only for the detection of protein 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 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

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.

• 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.

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

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

REF

LOT

FPO

For symbol glossary, refer to Instructions for Use.

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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

4 Tests

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

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

For symbol glossary, refer to Instructions for Use.

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

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 three times over five 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.

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.

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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.

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

Suitable for age 2+ years

Fast results in 20 minutes  
Easy testing

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

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

For symbol glossary, refer to Instructions for Use.

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.

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