A rapid test for the detection of SARS-CoV-2 antigens in anterior nasal specimens. For self-testing use. For use under an Emergency Use Authorization (EUA) only. Carefully read the instructions before performing the test. Failure to follow the instructions may result in inaccurate test results.

**TEST PROCEDURE**

1. **PREPARATION**
   - Wash or sanitize your hands. Make sure they are dry before starting the test.
   - Read the instructions.

2. **SPECIMEN COLLECTION**
   - Check your kit contents and make sure you have everything. Check the expiration date printed on the cassette.
   - Open the test cassette pouch and lay on a clean surface.

3. **COLLECTION BY AN ADULT**
   - Punch through the perforated circle on the kit box to form a tube holder. Place the tube in the tube holder.
   - Gently insert the entire absorbent tip of the swab head into 1 nostril (½ to ¾ of an inch). With children, the maximum depth of insertion into the nostril may be less than ¾ of an inch, and you may need to have a second person to hold the child’s head while swabbing.
   - Note: A false negative result may occur if the nasal swab specimen is not properly collected.

4. **RESULTS INTERPRETATION**
   - Immediately place the swab into the buffer tube. Swirl at least 30 seconds.
   - Note: A false negative result may occur if the swab is not swirled at least 30 seconds.
   - Firmly rub the swab in a circular motion around the inside wall of the nostril 5 times. Take approximately 15 seconds to collect the specimen. Be sure to collect any nasal drainage that may be present onto the swab. Repeat this in the other nostril.

5. **SELF COLLECTION**
   - A 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.
   - A nasal swab sample can be self-collected by an individual aged 2 to 13 years. Children aged 2 to 13 years should be tested by an adult.

6. **COLLECTION BY CHILDREN**
   - Place the tube in the tube holder.
   - Gently squeeze the tube and dispense 4 drops of solution into the Sample Well. Dispose the tube in the trash. Note: A false negative or invalid result may occur if less than 4 drops of fluid are added to the Sample Well.

7. **RESULT INTERPRETATION**
   - Only the control line (C) and no test line (T) appears. This means that SARS-CoV-2 antigen was detected.
   - Both the control line (C) and test line (T) appear. This means that SARS-CoV-2 antigen was detected.

8. **DISPOSE TEST KIT**
   - Dispose the test cassette in the trash. Note: Test samples must be disposed of immediately after collection, and no more than one hour after the swab is added to the reagent solution, if stored at room temperature.

9. **CLEAN UP**
   - Set the timer for 15 minutes. Result should be read at 15 minutes. Do not read after 30 minutes. Dispose the test cassette in the trash. Note: A false negative or false positive result may occur if the test result is read before 15 minutes or after 30 minutes.

10. **GERM-FREE DISPOSABLE SWAB**
    - Control line (C) fails to appear. Not enough specimen volume or incorrect orientation are the likely reasons for an invalid result. If a control (C) line is not visible, the test is invalid. Re-test with a new swab and new test device.

11. **RESULT INTERPRETATION**
    - Both the control line (C) and test line (T) appear. This means that SARS-CoV-2 antigen was detected.
    - A negative result indicates that antigens from the virus that causes COVID-19 were not detected in your test sample and it is very likely you have COVID-19 and are contagious. Please contact your doctor or 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). Your healthcare provider will work with you to determine how best to care for you based on your test results along with medical history and your symptoms.

12. **RESULT INTERPRETATION**
    - Both the control line (C) and test line (T) appear. This means that SARS-CoV-2 antigen was detected.
    - 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 or 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). Your healthcare provider will work with you to determine how best to care for you based on your test results along with medical history and your symptoms.

13. **RESULT INTERPRETATION**
    - Both the control line (C) and test line (T) appear. This means that SARS-CoV-2 antigen was detected.
    - A negative result indicates that antigens from the virus that causes COVID-19 were not detected in your test sample and it is very likely you have COVID-19 and are contagious. Please contact your doctor or 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). Your healthcare provider will work with you to determine how best to care for you based on your test results along with medical history and your symptoms.

14. **RESULT INTERPRETATION**
    - Both the control line (C) and test line (T) appear. This means that SARS-CoV-2 antigen was detected.
    - 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 or 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). Your healthcare provider will work with you to determine how best to care for you based on your test results along with medical history and your symptoms.

15. **RESULT INTERPRETATION**
    - Both the control line (C) and test line (T) appear. This means that SARS-CoV-2 antigen was detected.
    - 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 or 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). Your healthcare provider will work with you to determine how best to care for you based on your test results along with medical history and your symptoms.

16. **RESULT INTERPRETATION**
    - Both the control line (C) and test line (T) appear. This means that SARS-CoV-2 antigen was detected.
    - 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 or 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). Your healthcare provider will work with you to determine how best to care for you based on your test results along with medical history and your symptoms.

17. **RESULT INTERPRETATION**
    - Both the control line (C) and test line (T) appear. This means that SARS-CoV-2 antigen was detected.
    - 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 or 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). Your healthcare provider will work with you to determine how best to care for you based on your test results along with medical history and your symptoms.

18. **RESULT INTERPRETATION**
    - Both the control line (C) and test line (T) appear. This means that SARS-CoV-2 antigen was detected.
    - 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 or 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). Your healthcare provider will work with you to determine how best to care for you based on your test results along with medical history and your symptoms.

19. **RESULT INTERPRETATION**
    - Both the control line (C) and test line (T) appear. This means that SARS-CoV-2 antigen was detected.
    - 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 or 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). Your healthcare provider will work with you to determine how best to care for you based on your test results along with medical history and your symptoms.

20. **RESULT INTERPRETATION**
    - Both the control line (C) and test line (T) appear. This means that SARS-CoV-2 antigen was detected.
    - 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 or 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). Your healthcare provider will work with you to determine how best to care for you based on your test results along with medical history and your symptoms.
The On/Go One COVID-19 Antigen Home Test is intended for self-use or lay user testing another in nasal swab specimens directly from individuals within 7 days of symptom onset or without symptoms. The On/Go One COVID-19 Antigen Home Test does not differentiate between SARS-CoV and SARS-CoV-2. It is a lateral flow chromatographic immunoassay intended for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in anterior nasal swab specimens. 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 IVDs 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-3(b)(1), unless the declaration is terminated, or authorization is revoked sooner.

FOR FDA EMERGENCY USE AUTHORIZATION (EUA) ONLY

- This product has not been FDA cleared or approved but has been authorized under an EUA.
- 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 IVDs for detection and/or diagnosis of COVID-19.
- The On/Go One COVID-19 Antigen Home Test is provided for non-prescription home use with self-collected anterior nasal swab specimens directly from individuals aged 14 years and older or adult-collected anterior nasal samples directly from individuals aged 2 years or older.
- The On/Go One COVID-19 Antigen Home Test does not differentiate between SARS-CoV and SARS-CoV-2.
- Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen. This antigen is generally found in respiratory 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 other viral causes of symptoms.

FREQUENTLY ASKED QUESTIONS

Q: WHAT IS COVID-19?
A: COVID-19 is caused by the SARS-CoV-2 virus which is a new virus in humans causing a contagious respiratory illness. COVID-19 can present with mild to severe illness, although some people infected with COVID-19 may have no symptoms at all. Older adults and people of any age with underlying medical conditions have a higher risk of severe illness from COVID-19. Serious outcomes of COVID-19 include hospitalization and death. The SARS-CoV-2 virus can be spread to others even before a person shows signs or symptoms of being sick (e.g., fever, coughing, difficulty breathing, etc.). A full list of symptoms of COVID-19 can be found at the following link: https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html

Q: WHAT IS COVID-19 TESTING?
A: COVID-19 testing identifies SARS-CoV-2 nucleocapsid protein antigen. This antigen is found in respiratory samples during the acute phase of infection. Negative results do not rule out SARS-CoV-2 infection. It is possible for this test to give a negative result that is incorrect (false negative) in some people with COVID-19. This means that you could possibly still have COVID-19 even though the test is negative. For example, you may get a false negative result if you did not follow the test correctly or if the level of antigen from the virus causing COVID-19 is below the test limits. The amount of antigen in a sample may decrease the longer you have symptoms of infection. If you test negative and continue to experience symptoms of fever, cough and/ or shortness of breath you should seek follow up care with your healthcare provider. Your healthcare provider will consider the test result together with other aspects of your medical history (such as symptoms, possible exposures, and geographical location of places you have recently traveled) in deciding how to care for you. Your healthcare provider may suggest you need another test to determine if you have contracted the virus causing COVID-19. It is important that you work with your healthcare provider to help you understand the next steps you should take.

Q: WHAT ARE THE KNOWN POTENTIAL RISKS AND BENEFITS OF THIS TEST?
A: Potential risks include:
- Possible discomfort during sample collection.
- Possible incorrect test results (see Result Interpretation section).
Potential benefits include:
- The results, along with other information, can help you and your healthcare provider make informed decisions about your care.
- The results of this test may help limit the spread of COVID-19 to your family and others in your community.

Q: WHAT IS AN INVALID TEST RESULT?
A: An invalid test result indicates that antigens from the virus that causes COVID-19 were not found in your sample. A negative test result indicates that antigens from the virus that causes COVID-19 were not found in your sample. A negative test result may occur if a specimen is incorrectly collected or handled.

Q: WHAT IF YOU TEST NEGATIVE?
A: A negative test result indicates that antigens from the virus that causes COVID-19 were not found in your sample. If you have symptoms, you likely do not have COVID-19. However, negative results do not rule out SARS-CoV-2 infection. It is possible for this test to give a negative result that is incorrect (false negative) in some people with COVID-19. This means that you could possibly still have COVID-19 even though the test is negative. For example, you may get a false negative result if you did not follow the test correctly or if the level of antigen from the virus causing COVID-19 is below the test limits. The amount of antigen in a sample may decrease the longer you have symptoms of infection. If you test negative and continue to experience symptoms of fever, cough and/or shortness of breath you should seek follow up care with your healthcare provider. Your healthcare provider will consider the test result together with other aspects of your medical history (such as symptoms, possible exposures, and geographical location of places you have recently traveled) in deciding how to care for you. Your healthcare provider may suggest you need another test to determine if you have contracted the virus causing COVID-19. It is important that you work with your healthcare provider to help you understand the next steps you should take.

Q: WHAT IF YOU TEST POSITIVE?
A: A positive result means that it is very likely you have COVID-19 because from the virus causing COVID-19 were not found in your sample. You should get medical advice. https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html

Q: WHAT IS THE DIFFERENCE BETWEEN AN ANTIGEN AND MOLECULAR TEST?
A: There are different kinds of tests for the virus that causes COVID-19. Molecular tests detect genetic material from the virus. Antigen tests, such as the On/Go One COVID-19 Antigen Home Test, detect proteins from the virus. Antigen tests are very specific for the SARS-CoV-2 virus but are not as sensitive as molecular tests. This means that a positive result is highly accurate, but a negative result does not completely rule out infection. If your test result is negative, you should discuss with your healthcare provider whether another test is necessary and if you should continue isolating at home. There is a higher chance of false negative results with antigen tests than with laboratory-based molecular tests. This means that there is a higher chance this test will give you a negative result when you have COVID-19 than a molecular test would.

Q: HOW ACURATE IS THIS TEST?
A: The performance of On/Go One COVID-19 Antigen Home Test was established in an all-comers clinical study conducted between March 2021 and May 2021 with 172 nasal swabs self-collected or performed by trained personnel (108 individuals with COVID-19 onset) suspected of COVID-19 and 64 asymptomatic patients. All subjects were screened for the presence or absence of COVID-19 symptoms within two weeks of study enrollment. The On/Go One COVID-19 Antigen Home Test was compared to an FDA authorized molecular SARS-CoV-2 test. The On/Go One COVID-19 Antigen Home Test correctly identified 93% of positives and 100% of negative samples.

Q: WHAT IF YOU TEST NEGATIVE?
A: A negative test result indicates that antigens from the virus that causes COVID-19 were not found in your sample. If you have symptoms, you likely do not have COVID-19. However, negative results do not rule out SARS-CoV-2 infection. It is possible for this test to give a negative result that is incorrect (false negative) in some people with COVID-19. This means that you could possibly still have COVID-19 even though the test is negative. For example, you may get a false negative result if you did not follow the test correctly or if the level of antigen from the virus causing COVID-19 is below the test limits. The amount of antigen in a sample may decrease the longer you have symptoms of infection. If you test negative and continue to experience symptoms of fever, cough and/or shortness of breath you should seek follow up care with your healthcare provider. Your healthcare provider will consider the test result together with other aspects of your medical history (such as symptoms, possible exposures, and geographical location of places you have recently traveled) in deciding how to care for you. Your healthcare provider may suggest you need another test to determine if you have contracted the virus causing COVID-19. It is important that you work with your healthcare provider to help you understand the next steps you should take.

Q: WHAT DOES AN INVALID TEST RESULT MEAN?
A: An invalid result means the test was not able to tell if you have COVID-19 or not. If the test is invalid, a new swab should be used to collect a new nasal specimen and the test should be run again using a new test and tube.

IMPORTANT

This test is intended to be used as an aid in the clinical diagnosis of a current COVID-19. Do not use this test as the only guide to manage your illness. Please consult your healthcare provider if your symptoms persist or become more severe, or if you are concerned at any time.

Individuals should provide all results obtained with this product to their healthcare provider for public health reporting. If using the test, the test results can be shared via the On/Go App Passport.

HEALTHCARE PROVIDERS

Please visit www.letsongo.com to obtain the complete instructions for use and fact sheet for healthcare providers.

Index of Symbols

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- Do not reuse
- Do not use if the test is damaged or open
- Do not store or use beyond the date indicated on the package
- Do not use nasal sprays for at least 30 minutes before collecting a nasal sample
- Do not use if the expiration date has passed
- Do not use if the test is damaged or open
- Do not use on anyone who is prone to nosebleeds or has had facial injuries or head injuries/surgery in the past six months
- Do not touch the swab tip when handling the swab

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