GeneFinder™ COVID-19 Ag Home Test

For Investigational Use Only
The performance characteristics of this test have not been established.

Carefully read the instructions before performing the test. Failure to follow the instructions may result in inaccurate test results.

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.

Materials Provided

Instructions for use


Test cassette

Extraction buffer tube & Filter cap


Sterile Swab

Storage and Stability

Store the kit at 2 -30 °C / 36 -86 °F and protect from direct sunlight. The expiration date of the materials is indicated on the external packaging. Do not freeze the kit.

Prepare to Perform the Test

1 Bring test kit to room temperature(15-30 ºC / 59-86ºF).

****Before washing your hands, please prepare by blowing your nose.****

2 Wash your hands with soap and water, or use hand sanitizer before performing the test. Make sure you rinse thoroughly and your hands are dry before starting.

3 Check test expiration date on the back of the foil pouch. Do not use if the expiry date has passed.

NOTE: Testing should commence immediately after opening the sealed pouches

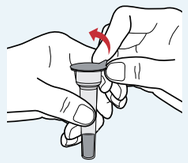
4 Open the pouch and remove the test device from the foil pouch.

5 Place the test device on a flat surface.

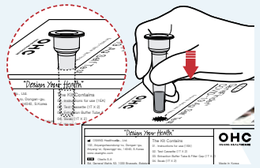
Test Procedure

1 Open the pouch that contains the extraction buffer tube & filter cap.

Open the seal of the tube carefully without spilling the liquid inside the tube.



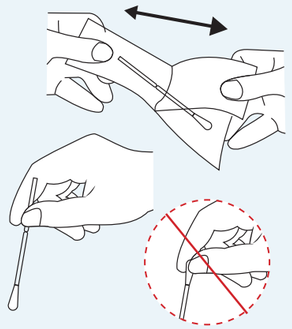
Punch a hole in the box to hold the tube.



If any liquid spills, do not use the tube.

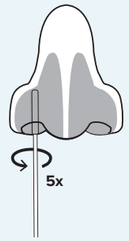
2 Remove the swab from the packaging.

Ensure that you only touch the handle of the swab and not the soft pad at the tip.



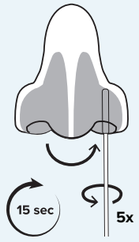
3 Holding the stick end of the swab, gently insert the foam end of the swab into the nostril approximately ¾ inch.

****Swab Both Nostrils****



4 **Firmly and slowly** rotate the swab **at least 5 times,** brushing against the inside walls of the nostril at least 5 times for a total of **15 seconds**.

****Do not just spin the swab.****



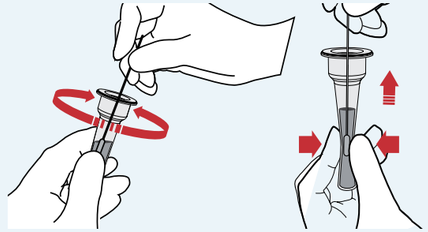
Gently remove the swab and, using the same swab, repeat in the second nostril with the same end of the swab.

NOTE: 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.

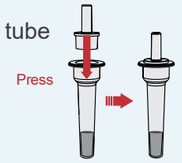
WARNING! Inaccurate test results may occur if the nasal swab specimen is not properly collected.

5 Directly Insert the sterile swab taken from the nostril into the extraction buffer tube and stir it more than 10 times.
Take out the swab from the extraction buffer tube by squeezing and applying pressure on both sides of the tube.

WARNING! Failure to squeeze the tube can lead to incorrect results due to excess buffer in the swab.

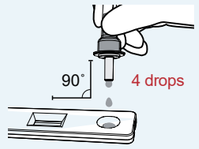


6 Dispose of the swab and seal the tube securely with the nozzle cap.



7 Hold the tube upright above the sample well.

Drop 4 drops onto the sample well.



****Do not apply the liquid in the rectangular result window****

8 Set the timer and read the test result at 15 minutes. Do not read the result after 20 minutes.

Read test result at 15 minutes.

DO NOT read after 20 minutes.

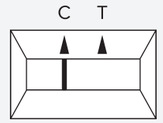
WARNING! Do not move or lift the test device during this time.

After test is completed, dispose of used materials in household trash. Do not flush or pour test liquids down a drain.

Read and Interpret the Results

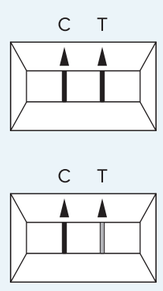
WARNING! Inaccurate test interpretations may occur if results are read before 15 minutes or after 20 minutes.

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.



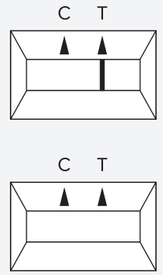
◂ Negative result

If a control line (C) is visible (regardless of how faint it is) and a test line (T) is not visible, this means that the result is negative. It is unlikely that you have COVID-19. However, even if your test is negative, continue to observe all hygiene and safety measures. If you suspect that you have an infection (i.e., if you have prolonged symptoms or if your symptoms are worsening), contact your doctor/primary care physician. You may have another infection, or your test result may be false. Negative results do not rule out COVID-19. This means you could possibly still have COVID-19 even though the test is negative. If you do not have COVID-19 symptoms and your result is negative, you should test again with at least 24 hours and no more than 48 hours between tests.



◂ Positive result

If a test line (T) is visible together with a control line (C), this means that the result is positive. Look carefully at the result: **The test should be considered positive if two lines are visible - even if they are faint.** A positive test result means it is very likely that you have COVID-19. Please contact your doctor/primary care physician or your local health authority immediately and adhere to the local guidelines regarding self-isolation. Your doctor may require you to undergo a molecular PCR test to confirm the result. 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, the result must be considered invalid. The test is not working correctly and you should perform another test using a different test kit. You may have performed the test incorrectly. Carefully read the Quick Reference Instructions and repeat the test. If your test result is still invalid, please contact your doctor or a COVID-19 test center.

version 2.1 Effective Date: 2021-December 29 2021

Proposed Intended Use

The GeneFinder™ COVID-19 Ag Home Test is a single-use rapid lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 from individuals with or without symptoms or other epidemiological reasons to suspect COVID-19 infection.
The GeneFinder™ COVID-19 Ag Home Test is intended to detect nucleocapsid protein antigen from the SARS-CoV-2 virus that causes COVID-19, in human nasal swab samples that are self-collected by an individual aged 14 years or older or are collected by an adult from an individual age 2 years and older within the first 7 days of symptom onset or without symptoms or other epidemiological reasons to suspect COVID-19 infection.

The GeneFinder™ COVID-19 Ag Home Test does not differentiate between SARS-CoV and SARS-CoV-2.

Persons who test positive with the GeneFinder™ COVID-19 Ag Home Test should self-isolate and should seek follow up care with their physician or healthcare provider as additional testing and public health reporting may be necessary. Positive results do not rule out bacterial infection or co-infection with other viruses. Persons 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.

Results are for the identification of SARS-CoV-2 nucleocapsid antigen. Antigen is generally detectable in human anterior nasal (nares) swab 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. The agent detected may not be the definite cause of disease. Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities.

Negative results should be treated as presumptive, and 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 decisions. Negative results should be considered in the context of a patient's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19, and confirmed with a molecular assay, if necessary, for patient management.

Individuals should provide all results obtained with this product to their healthcare provider for public health reporting. 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 GeneFinder™ COVID-19 Ag Home Test is intended for self-use and/or, as applicable for a lay user testing another person in a non-laboratory setting.

Warnings and Precautions

Read instructions carefully before performing a test. Failure to follow directions may produce inaccurate test results.

- Use the test kit once only. Do not use with multiple specimens.
- The test is intended to aid in the diagnosis of a current COVID-19 infection. Please consult a healthcare professional to discuss your results and if any additional testing is required.
- Keep test kit and materials out of the reach of children and pets before and after use. If ingested, seek medical advice.
- Do not use on anyone under two years of age.
- Do not open the kit contents until ready for use. If the test cassette is open for an hour or longer, invalid test results may occur.
- Do not use the test after the expiration date shown on the test cassette pouch.
- Do not use the test if the pouch is damaged or open.
- Make sure there is sufficient light when testing.
- Do not use nasal sprays for at least 30 minutes before collecting a nasal sample
- In the event of a spillage, ensure that it is cleaned thoroughly using a suitable disinfectant.
- Use only the component of this test kit.
- If you suspect the presence of blood on the swab, discard the swab and repeat the test with a fresh one.
- Remove any piercings from the nose before starting the test.
- Do not use on anyone who is prone to nosebleeds or has had facial injuries or head injuries/ surgery in the past six months.
- Inadequate or improper nasal swab sample collection may yield false negative test results.
- Do not touch the swab head when handling the swab.
- The test is intended to be read at 15 minutes. **If the test is read before 15 minutes or after 20 minutes, false negative or false positive results may occur, and the test should be repeated with a new test cassette.**
- Do not ingest any kit components.
- Avoid exposure of your skin, eyes, nose, or mouth to the solution in the extraction tube.
- The chemicals in the reagent solution are hazardous to the skin and eye. Please see the below table for safety recommendations for skin and eye irritation. No personal protective equipment is recommended for use.

Hazard Category (mixture)	Hazard Statement for Mixture	Labeling of Harm(s)
Not classified	Acute oral or dermal toxicity	None
Category 2	Eye irritation	May cause eye irritation
Category 3	Skin irritation	Causes mild skin irritation

- If the reagent solution contacts the skin or eye, flush with plenty of water. If irritation persists, seek medical advice. https://www.poison.org/contact-us or 1-800-222-1222

Limitations

- The test procedure, precautions and interpretation of results for this test must be followed strictly when testing.
- The test should be used for the detection of SARS-CoV-2 antigen in human nasal swab samples.
- This is a qualitative test, therefore quantitative values of SARS-CoV-2 antigen concentration cannot be determined.
- False negative test results (i.e., an existing infection is not detected) may occur if the antigen level in the specimen is less than the minimum detection limit of the test.
- False negative test results may occur if the specimen swab is not mixed well in the tube (step 5 in the test procedure section).
- The immune response cannot be evaluated using this test.Other test methods are required for that purpose.
- The test does not differentiate between SARS-CoV and SARS-CoV-2.

Frequently Asked Questions

Q: WHAT IS COVID-19?
A: COVID-19 is an acute respiratory infectious disease caused by the SARS-CoV-2 virus, a novel Betacoronavirus. SARS-CoV-2 is mostly spread person-to-person, both by individuals with symptoms of COVID-19 infection and by infected people without symptoms. Based on the current knowledge, the incubation period is 1 to 14 days, mostly 4-5 days. Symptoms include fever, fatigue, and cough. For a full list of symptoms, see: https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html

Q: WILL THIS TEST HURT?
A: No, the nasal swab is not sharp, and it should not hurt. Sometimes the swab can feel slightly uncomfortable. If you feel pain, please stop the test and seek advice from your healthcare provider.

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 THE DIFFERENCE BETWEEN AN ANTIGEN AND MOLECULAR TEST?
A: There are different kinds of tests for COVID-19. Molecular tests (also known as PCR tests) detect genetic material from the virus. Antigen tests, such as the GeneFinder™ COVID-19 Ag Home Test detect proteins from the virus. Antigen tests are very specific for the COVID-19 virus but are not as sensitive as molecular tests. This means that a positive result is highly accurate, but a negative result does not rule out infection. 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. If your test result is negative, you should discuss with your healthcare provider whether an additional molecular test is necessary and if you should continue isolating at home.

Q: HOW ACCURATE IS THIS TEST?
A: The performance of GeneFinder™ COVID-19 Ag Home Test was established in an all-comers clinical study conducted between .....To be completed

Q: WHAT IS SERIAL TESTING?
A: Serial testing is when one person tests themselves multiple times for COVID-19 on a routine basis, such as every day or every other day. By testing more frequently, you may detect COVID-19 more quickly and reduce spread of infection. Serial testing (i.e. testing every day or every other day) is more likely to detect COVID-19,especially when you do not have any symptoms. Testing for asymptomatic individuals should be performed at least twice over three days, with at least twenty-four hours and no more than 48 hours between tests. You may need to purchase additional tests to perform this serial (repeat) testing.

Q: WHAT IF YOU TEST POSITIVE?
A: A positive test result means that antigens from COVID-19 were detected and it is very likely you currently have COVID-19 disease. There is a very small chance that this test can give a positive result that is wrong (a false positive result). If you test positive you should self-isolate at home per CDC recommendations to stop spreading the virus to others. Please consult the CDC recommendations regarding self-isolation at www.cdc.gov/coronavirus. Seek follow-up care with your healthcare provider immediately. Your healthcare provider will work with you to determine how best to care for you based on your test result(s) along with your medical history, and your symptoms.

Q: WHAT IF YOU TEST NEGATIVE?
A: A negative test result indicates no antigens for COVID-19 were detected. It is possible for this test to give a negative result that is incorrect (false negative) in some people with COVID-19, and negative results are presumptive and may need to be confirmed with a molecular test. This means that you could possibly still have COVID-19 even though the test is negative. 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 immediately. Your healthcare provider may suggest you need another test to determine if you have contracted the virus causing COVID-19. If you are concerned about your COVID-19 infection status after testing or think you may need follow up testing, please contact your healthcare provider.

Important

This test is intended to be used as an aid in the clinical diagnosis of a current COVID-19 infection. 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.

Index of Symbols

REF	Reference number		Date of manufacture
IVD	In Vitro Diagnostics		Use by date
SELF-TESTING	Self-testing used		Caution
LOT	Batch code		Temperature limut
	Manufacturer		Do not re-use
	Contains sufficient for <n>testes.		Keep dry
	Consult Instruction for use.		Keep away from sunlight
	Do not use if packaging is damaged		

MANUFACTURE
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Manufacturer and Authorized representative information for sterile swabs is as below.

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