

CLEARDETECT™
COVID-19
Antigen Home Test

User Instructions

For Emergency Use Authorization (EUA) Only.
In vitro diagnostic use only.
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. For more information on EUAs please visit: <https://www.fda.gov/emergency-preparedness-andresponse/mcmlegal-regulatory-and-policy-framework/emergency-use-authorization>
For the most up to date information on COVID-19, please visit: www.cdc.gov/COVID19

Intended Use

The MaximBio ClearDetect™ COVID-19 Antigen Home Test is a rapid lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2. This test is authorized for non-prescription home use with self-collected anterior nasal (nares) swab samples from individuals aged 14 years or older with symptoms of COVID-19 within the first 5 days of symptom onset. This test is also authorized for non-prescription home use with adult-collected anterior nasal (nares) samples from individuals aged 2 years or older with symptoms of COVID-19 within the first 5 days of symptom onset. This test is also authorized for non-prescription home use with self-collected anterior nasal (nares) samples from individuals aged 14 years or older, or adult-collected anterior nasal swab samples from individuals aged 2 or older, with or without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over three days with at least 24 hours (and no more than 48 hours) between tests. The MaximBio ClearDetect™ 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. Antigen is generally detectable in anterior nasal (nares) swab specimens 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 definite cause of disease. Individuals who test positive with the MaximBio ClearDetect™ COVID-19 Antigen Home Test should self-isolate and seek follow up care with their physician or healthcare provider as additional testing may be necessary. Negative results should be treated as 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 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. For serial testing programs, additional confirmatory testing with a molecular test for negative results may be necessary, if there is a high likelihood of SARS-CoV-2 infection, such as in an individual with a close contact with COVID-19 or with suspected exposure to COVID-19 or in communities with high prevalence of infection. Additional confirmatory testing with a molecular test for positive results may also be necessary, if there is a low likelihood of SARS-CoV-2 infection, such as in individuals without known

exposures to COVID-19 or residing in communities with low prevalence of infection. 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. 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 MaximBio ClearDetect™ COVID-19 Antigen Home Test is authorized for non-prescription self-use and/or as applicable for an adult lay user testing another person 2 years or older. The MaximBio ClearDetect™ COVID-19 Antigen Home Test is only for use under the Food and Drug Administration's Emergency Use Authorization.

Warnings, Precautions and Safety

1. This test is intended to aid in the diagnosis of a current SARS-CoV-2 infection. Please consult a healthcare professional to discuss your results and if any additional testing is required.
2. Read this product insert completely before performing the test and follow the instructions carefully to avoid obtaining inaccurate results.
3. Keep kit contents out of the reach of children and pets before and after use.
4. You should wear a face mask if swabbing others.
5. Do not use kit past the expiration date printed.
6. All kit contents are intended for single use. Do not reuse. Do not use with multiple specimens.
7. Use only the components of this test kit. Do not mix components from different kit lots.
8. Do not open the Test Strip pouch packaging until ready to perform a test. Use immediately.
9. Inadequate or improper specimen collection and handling may yield false negative results. Collect specimen and immediately perform test according to instructions.
10. Do not touch swab head (specimen collection area) while handling the swab.
11. Ensure Test Strip remains upright throughout the duration of the test. Improper handling and setup may yield inaccurate results.
12. Avoid handling the results window (i.e., membrane) of the Test Strips to minimize contamination.
13. This test is read visually. Individuals with impaired vision or color-impaired vision may not be able to adequately interpret test results.
14. Wash hands thoroughly or use hand sanitizer after handling.
15. Dispose of kit contents and patient samples in household trash.
16. Use the test kit once only. Do not use with multiple specimens.
17. This is a qualitative test, therefore quantitative values of SARS-CoV-2 antigen concentration cannot be determined.
18. 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.
19. False negative test results may occur if the specimen swab is not mixed well in the tube (step 6 in the test procedure section).
20. The immune response cannot be evaluated using this test. Other test methods are required for that purpose.
21. The test does not differentiate between SARS-CoV and SARS-CoV-2.
22. Do not use if any of the test kit contents or packaging is damaged or open.
23. Make sure there is sufficient light when testing.
24. Children aged 2 to 13 years of age should not swab themselves and should instead be tested by an adult.
25. Do not use on anyone under 2 years of age.
26. Do not use nasal sprays for at least 30 minutes before collecting a nasal sample.
27. Do not use on anyone who is prone to nosebleeds or has had facial injuries/surgery in the past six months.
28. If you suspect there is blood on the swab, discard the swab, make sure you are not bleeding, and repeat the test with a fresh one.
29. The control line may show up within a few minutes of starting the test. It may take up to 15 minutes for a test line to show up.
30. Avoid contact with your skin, eyes, nose, or mouth.
31. Do not ingest any kit contents.
32. Use of gloves is recommended when conducting testing.
33. The extraction solution in the vial contains potentially harmful chemicals. If the solution contacts the skin or eye, flush with copious amounts of water. If irritation persists, seek medical advice: <https://www.poisson.org/contact-us> or 1-800-222-1222.

Hazard Category (mixture)	GHS Hazard Statement for mixture	Labeling of Harm(s)	Hazardous Ingredients (%)	Recommended PPE Statement
Category 1	Skin sensitization	May cause an allergic skin reaction (H317)	Microcide III (0.2%)	Gloves
Category 2	Eye irritation	Causes eye irritation (H320)	Tris Base (0.242%) Tris-HCl (0.314%) Sodium chloride (1.75%) NP-40 (0.6%) Microcide III (0.2%)	NA
Category 3	Skin irritation	Causes mild skin irritation (H316)	Tris Base (0.242%) Tris-HCl (0.314%) NP-40 (0.6%) Microcide III (0.2%)	NA

Frequently Asked Questions

What is COVID-19?

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>

Will this test hurt?

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 a healthcare provider.

What are the known and potential risks and benefits of this test?

Potential risks include:

- Possible discomfort during sample collection.
- Possible incorrect test results (see Interpret Results section).

Potential benefits include:

- The results, along with other information, can help your healthcare provider make informed recommendations about your care.
- The results of this test may help limit the spread of COVID-19 to your family and others in your community.

What is the difference between an antigen and molecular test?

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 MaximBio ClearDetect™ 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 rule out infection. If your test result is negative, you should discuss with your healthcare provider whether an additional 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.

How accurate is this test?

The performance of the MaximBio COVID-19 Antigen Home Test was established in a prospective clinical study using an EUA authorized molecular test as a comparator method (PPA (86.9%) and NPA (98.9%)). You can find further information by visiting www.maximbio.com. The performance of this test is still being studied in patients without signs and symptoms of respiratory infection and for serial screening. Performance may differ in these populations.

What if you test positive?

A positive test result indicates that antigens from the virus that causes COVID-19 were found in your sample and it is very likely you currently have COVID-19. 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 along with your medical history, and your symptoms.

What if you test negative?

A negative test result means that proteins from the virus that causes COVID-19 were not found in your sample. If you have symptoms, you likely do not have COVID-19. If you do not have symptoms and you receive a second negative result 24 to 48 hours after your first negative result, then you are likely not infected with COVID-19. It is possible for this test to give a negative result that is incorrect (false negative) in some people with COVID-19. This means you could possibly still have COVID-19 even though the test is negative. The amount of antigen in a sample may decrease the longer you have symptoms of infection. If you test after you have had symptoms for more than 7 days, your results are likely to be negative compared to a molecular assay. If you test negative and continue to experience COVID-19-like symptoms of fever, cough and/or shortness of breath, you should seek follow up care with your healthcare provider. 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.

Is the solution in the tube harmful?

No. The solution in the tube (sample buffer) contains potentially harmful chemicals; however, laboratory studies have shown them to be nontoxic at the levels contained in the solution. The solution should only be used as directed. Do not ingest. Keep out of reach of children. Avoid contact with eyes and skin.

What does an invalid test result mean?

If no control line shows up on the test, the result is invalid (even if any test line shows up). 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 all new test components.

What is serial testing?

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.

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.











Serial Testing Information and Limitations

- If you have symptoms of COVID-19 that started within the last 5 days, you can use a single test.
- Testing for asymptomatic individuals should be performed at least twice over three days, with at least 24 hours and no more than 48 hours between tests. You may need to purchase additional tests to perform this serial (repeat) testing.
- For serial testing, if your first test result is negative, you should test again with a new test in 24 to 48 hours.
- 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.
- If your first or second test is positive, then proteins from the virus that causes COVID-19 have been found in your sample and you likely have COVID-19.
- If both your first and second tests are negative, you may not have COVID-19, however you should follow-up with your healthcare provider if you are at high risk for COVID-19.


Storage and Stability

Store the MaximBio ClearDetect™ COVID-19 Antigen Home Test Kit between 4-30°C (39.2-86°F). Ensure all kit contents are at room temperature before use. Kit contents are stable until the expiration date printed on the outer packaging. Do not use beyond the expiration date. The Test Strip must remain in the sealed pouch until use.

Symbols

	Catalog Number		In vitro diagnostic use only
	Lot Number (Batch Code)		Tests Per Kit
	Use by (Expiration Date)		Manufacturer
	Temperature Limitations (Storage Temperature)		Date of Manufacture
	One Time Use (Single Use Only)		Consult Instructions for Use

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