Interpret the Results

**COVID-19 Positive (+)**

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

**COVID-19 Negative (-)**

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 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.

**Invalid**

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

**Negative**

If the Control (C) line and the Test (T) line are not visible, the test is invalid. You do not need to perform repeat testing.

**Positive**

If the Control (C) line and the Test (T) line are visible, the test is 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).

**Warning**

- False results may occur if the test is read outside the recommended time period. When reading test results, remove the test strip from the tube if necessary.
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The MaximBio ClearDetect™ COVID-19 Antigen Home Test is a lateral flow immunoassay device intended for the qualitative detection of nucleocapsid protein antigens from SARS-CoV-2 in nasal or nasal/oropharyngeal swabs.

This test is authorized for non-prescription home use with self-collected anterior nasal (nares) swab samples from individuals aged 14 or older and adult collected anterior nasal (nares) swab samples from individuals aged 2 years or older. This test is authorized for emergency use by the FDA under Authorization (EUA) within the first 3 days of symptom onset when tested at least twice over the next 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 MaximBio ClearDetect™ COVID-19 Antigen Home Test does not differentiate between SARS-CoV or SARS-CoV-2.

Results are for the identification of SARS-CoV-2 nucleocapsid protein antigens, which is generally detectable in anterior nasal swabs 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. Possible incorrect test results may be reflective of the prevalent variants in circulation at the time of testing.

The results, along with other information, can help your healthcare provider make informed recommendations about your care.

Warnings, Precautions and Safety

• Read all instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate test results.
• In cases where a test result is positive for COVID-19 under the EUA, the results must be reported to your healthcare provider. If an invalid result is obtained, the test should be repeated.

Frequently Asked Questions (Cont’d)

How accurate is this test? Clinical studies have shown that antigen tests more accurately determine whether you are infected with the coronavirus 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 Limited Use Declaration and the performance data in the Healthcare Provider Instructions for Use (IFU), available at www.maximbio.com.

What if I have a positive test result? A positive test 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 test 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 a negative test result and you test again in 48 hours and still have symptoms and a negative test result, you may not have COVID-19, however you should still follow up with your healthcare provider.

What is the difference between an antigen and molecular test? There are different kinds of tests used to detect genetic material from the virus. Antigen tests, such as the maximbio ClearDetect™ COVID-19 Antigen Home 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 negative result when you have COVID-19 than a molecular test would.
In the USA, this product has not been FDA cleared or approved; but has been authorized by FDA under EUA. For more information on expiration dating for COVID-19 antigen tests, please refer to http://www.fda.gov/covid-tests.

This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens; and

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.

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For in vitro diagnostic use.

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.

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.

COVID-19 Antigen Home Test

Contents:

- 1 Nasal Swab
- 1 Test Strip
- 1 Sample Buffer Tube
- 1 User Instructions

Maxim Biomedical, Inc.
1500 East Gude Drive, Suite A
Rockville, MD 20850 USA
www.maximbio.com
301-251-0800

COVID-19
Antigen Home Test

For Emergency Use Authorization (EUA) only

For symbol glossary, please refer to Instructions for Use
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