**MaximBio**

**CLEARDETECT™ COVID-19 Antigen Home Test**

**User Instructions**

Carefully read the instructions prior to starting test. It is recommended that gloves (not provided) be used during testing.

1. **Prepare for Test**

- Check the test expiration ( ) printed on the kit box. Wash or sanitize your hands. Make sure they are dry before starting. Ensure space is clean prior to testing. Required testing components:
  - 1 Test Strip in Pouch
  - 1 Tube of Sample Buffer (not included)
  - Timer

2. **Stand Up Tube & Remove Cap**

- Place the tube upright in the tube holder/stand.
- Remove cap - DO NOT discard.
- Save the cap for use in Step 9.

3. **Open Swab**

- Do not touch the swab tip.
- Open the swab packaging at stick end.
- Take out swab.

4. **Swab Both Nostrils**

- Gently insert the swab tip into one nostril about \( \frac{1}{2} \) to \( \frac{3}{4} \) of an inch. Do not insert the swab any further if you feel any resistance.
- Using medium pressure, rub the swab tip against the inside wall of the one nostril.
- Make at least 5 large circles (about 15 seconds). Do not just spin the swab.

5. **Swab Other Nostril**

- Using the same swab, repeat Step 4 in the other nostril.
- Note: Both nostrils must be swabbed to ensure accurate results. Note: If you are swabbing others, please wear a face mask. 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 steady the child’s head while swabbing.

6. **Insert Swab Into Tube & Mix**

- Completely submerge swab tip into the liquid inside the tube and set a 30 second timer. Repeatedly plunge for 30 seconds (approximately 30-60 plunges) or more. Mix by firmly pressing the swab tip to the bottom of the tube with each down motion.
- Repeat for 30 seconds (30-60 plunges)

7. **Break Swab**

- Make sure the swab tip is in the liquid inside of the tube. While using one hand to securely hold the tube down, use the other hand to carefully break the swab handle against the side of the tube. Discard the swab handle and leave the broken swab tip in the tube.

8. **Insert Test Strip**

- Open the test strip pouch carefully at tear notch and hold the test strip as shown.
- Hold the “MaximBio COVID-19” side of the test strip and carefully place it into the tube, facing upwards, so the results window is clearly visible.

9. **Securely Cap the Tube**

- Keep tube UPRIGHT during entire test.
- Make sure the test strip touches the bottom of the tube. While keeping the tube upright, secure the cap on the tube.

10. **Wait 15 Minutes**

- Do NOT disturb tube during this time.
- Read results at 15 minutes with good lighting.
- Do not read results before 15 minutes or after 30 minutes. If tube is disturbed prior to or during the 15 minute wait time, restart test from Step 1.

11. **Dispose In Trash**

- All used components should be disposed of in household trash.

**INTERPRET RESULTS**

**Check for Positive COVID-19 Result**

If a Control (C) line and the Test (T) line are visible, the test is positive. A faint visible reddish pink test (T) line with the control line (C) should be read as positive. A positive test result means that the virus that causes COVID-19 was detected in your sample, and you are very likely to have COVID-19. There is a very small chance that this test can give a positive result that is incorrect (a false positive). Please seek care with your healthcare provider as additional testing may be necessary. Your healthcare provider will work with you to determine how best to care for you based on your test results, medical history, and symptoms.

You should also self-isolate at home and avoid contact with others to avoid spreading the virus to others.

**Check for Negative COVID-19 Result**

If the Control (C) line is visible, but the Test (T) line is not visible, the test is negative. A negative test means that the virus that causes COVID-19 was not detected in your sample and it is unlikely you have COVID-19. However, even if your test is negative, continue to observe all hygiene and safety measures. If you test negative and continue to experience COVID-19 like symptoms (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 with all other aspects of your history such as symptoms and possible exposures to decide how to care for you. For example, your healthcare provider may suggest you need another test to determine if you have the virus causing COVID-19. It is important you work with your healthcare provider to help you understand the next steps you should take. Negative results do not rule out SARS-CoV-2 infection. This means that you could still possibly have COVID-19 even though the test is negative. If you do not have symptoms and your result is negative, you should test again with at least 24 hours and no more than 48 hours between tests.

**Check for Invalid COVID-19 Result**

If a control (C) line is not visible, even if a test line is visible, the test is invalid. A test that gives an invalid result means you need to test again with at least 24 hours and no more than 48 hours between tests. A new device and new tube. If the test is still invalid, contact your doctor.

**False results may occur if the test is read outside the recommended time period.**

Note: When reading test results, remove the test strip from the tube if necessary.

**Results Window**

**Positive**

- **Control (C) line and Test (T) line are visible.**

**Negative**

- **Control (C) line is visible, but the Test (T) line is not visible.**

**Invalid**

- **Control (C) line is not visible.**
In vitro diagnostic use only. Avoid handling the results window (i.e., membrane) to minimize contamination. Ensure Test Strip remains upright throughout the duration of the test. Improper handling can result in invalid results. Make sure there is sufficient light when testing. The control line may show up within a few minutes of starting the test. It may take up to 5 minutes for the test result to appear. False negative test results (i.e., an existing infection is not detected) may occur if the antigen is present but not moving in the test mixture. Do not use this test on anyone under 2 years of age. Do not ingest any kit contents. Do not touch swab head (specimen collection area) while handling the swab. False negative test results may occur if the specimen swab is not mixed well in the tube or if the swab is not properly inserted into the test. Do not use on anyone under 2 years of age.

The MaximBio ClearDetect™ COVID-19 Antigen Home Test does not differentiate between SARS-CoV-2 and other coronaviruses (COCVs). Molecular tests are required to determine if similar symptoms are caused by another virus. 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 testing. Performance may differ in these populations. What is the difference between an antigen and molecular test? Antigen tests, such as the MaximBio ClearDetect™ COVID-19 Antigen Home Test, detect proteins from the virus. Antigen tests are more specific than molecular tests. Molecular tests are more sensitive than antigen tests. 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 testing. Performance may differ in these populations.

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 and by infected people who have no symptoms. Even when people are not feeling sick, the virus is present in the respiratory secretions and on the skin surface of their nose and mouth. The virus is most easily spread by droplets when an infected person coughs, sneezes, speaks, or breathes. 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 and by infected people who have no symptoms. Even when people are not feeling sick, the virus is present in the respiratory secretions and on the skin surface of their nose and mouth. The virus is most easily spread by droplets when an infected person coughs, sneezes, speaks, or breathes.

Coughing, sneezing, speaking, or breathing can contaminate nearby surfaces, especially hard surfaces like tables, doorknobs, and light switches. The virus can remain infectious on these surfaces for hours to days. The virus is most easily spread by droplets when an infected person coughs, sneezes, speaks, or breathes. 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 and by infected people who have no symptoms. Even when people are not feeling sick, the virus is present in the respiratory secretions and on the skin surface of their nose and mouth. The virus is most easily spread by droplets when an infected person coughs, sneezes, speaks, or breathes.
In the USA, this product has not been FDA cleared or approved; but has been authorized by FDA under EUA. 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 exists justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under 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.

The ClearDetect COVID-19 Antigen Home Test is a lateral flow immunoassay that uses antibodies to detect nucleocapsid protein (nCP) from SARS-CoV-2. When used as a single test, it is intended for use in individuals who are suspected of having COVID-19 based on clinical symptoms and exposure history. When used serially on two separate specimens collected at least 24 hours apart, this test may be used to help suspect COVID-19 in asymptomatic individuals who are at high risk of exposure.

If you have symptoms of COVID-19, you can use a single test. If you do not have symptoms of COVID-19, you will need at least two tests per person. You may need to purchase additional tests to perform serial testing. This test does NOT determine if you had COVID-19 in the past or if you have immunity.

For symbol glossary, please refer to Instructions for Use.
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For in vitro diagnostic use. The ClearDetect™ COVID-19 Antigen Home 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... to suspect COVID-19 when tested twice over three days with at least 24 hours (and no more than 48 hours) between tests.

If you have symptoms of COVID-19, you can use a single test. If you do not have symptoms of COVID-19, you will need at least two tests per person. You may need to purchase additional tests to perform serial testing. This test does NOT determine if you had COVID-19 in the past or if you have immunity.

For use under the FDA Emergency Use Authorization (EUA) only.

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Rockville, MD 20850 USA
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For use under the EUA, the information is required to be true and correct, and in writing, and it is authorized.

COVID-19 Antigen Home Test

Contents:
• 2 Nasal Swabs
• 2 Test Strips
• 2 Sample Buffer Tubes
• 1 User Instructions

Ages 2 and up
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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 42 U.S.C. § 248d-4m, and is only authorized for use with Original EUA issued on Dec 14, 2020. The declaration, under Section 42 U.S.C. § 248d-4m of the Public Health Services Act, that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of SARS-CoV-2 is authorized only for use with the Original EUA. This product has not been reviewed by the FDA to confirm the product meets all FDA requirements to ensure safety, efficacy, and quality. The manufacturer is responsible for developing and maintaining full documentation of validation studies, including but not limited to, sensitivity and specificity data. The FDA has not cleared or approved this product. The FDA has not reviewed this product to establish its safety and effectiveness. The FDA has not determined if this product is safe and effective. Use of this product may result in permanent and severe adverse health consequences. The user is responsible for validating this product on their site and for any necessary validation and quality control procedures. The FDA has not reviewed this product and has not determined if this product is safe and effective. Use of this product may result in permanent and severe adverse health consequences. The user is responsible for validating this product on their site and for any necessary validation and quality control procedures. The FDA has not reviewed this product and has not determined if this product is safe and effective. Use of this product may result in permanent and severe adverse health consequences. The user is responsible for validating this product on their site and for any necessary validation and quality control procedures. 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