User Instructions

**Prepare for Test**

1. Check the test expiration (X) printed on the kit box. Wash or sanitize your hands. Make sure they are dry before starting.
2. Place the tube upright in the tube holder/stand.
3. Open the swab packaging at stick end.
4. Take out swab.
5. 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 break the swab handle against the side of the tube. Discard the swab 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.
6. Insert Swab Into Tube & Mix
   - Completely submerge swab tip into the liquid inside of the tube and set at 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).

**Swab Both Nostrils**

- Gently insert the swab tip into one nostril about ½ to ¾ of an inch. Do not insert the swab any further if you feel any resistance.
- Make at least 5 large circles (about 15 seconds). Do not just spin the swab.

**Swab Other Nostril**

- Using the same swab, repeat Step 4 in the other nostril.
- Note: Both nostrils must be swabbed to ensure accurate results.

**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.

**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.

**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 outwards, so the results window is clearly visible.

**Securely Cap the Tube (continued)**

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

**Wait 15 Minutes (continued)**

- 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.

**Insert Test Strip (continued)**

- 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 outwards, so the results window is clearly visible.

**Securely Cap the Tube (continued)**

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

**Wait 15 Minutes (continued)**

- 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.

**Insert Test Strip (continued)**

- 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 outwards, so the results window is clearly visible.

**Securely Cap the Tube (continued)**

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

**Wait 15 Minutes (continued)**

- 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.

**Insert Test Strip (continued)**

- 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 outwards, so the results window is clearly visible.

**Securely Cap the Tube (continued)**

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

**Wait 15 Minutes (continued)**

- 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.

**Insert Test Strip (continued)**

- 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 outwards, so the results window is clearly visible.

**Securely Cap the Tube (continued)**

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

**Wait 15 Minutes (continued)**

- 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.

**Insert Test Strip (continued)**

- 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 outwards, so the results window is clearly visible.

**Securely Cap the Tube (continued)**

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

**Wait 15 Minutes (continued)**

- 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.

**Insert Test Strip (continued)**

- 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 outwards, so the results window is clearly visible.

**Securely Cap the Tube (continued)**

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

**Wait 15 Minutes (continued)**

- 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.

**Insert Test Strip (continued)**

- 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 outwards, so the results window is clearly visible.

**Securely Cap the Tube (continued)**

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

**Wait 15 Minutes (continued)**

- 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.
For the most up to date information on COVID-19, please visit: www.cdc.gov/COVID19

The MaximBio ClearDetect™ COVID-19 Antigen Home Test is authorized for non-prescription home use with self-collected 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 self-collected anterior nasal (nares) swab samples from individuals aged 2 years or older with symptoms of COVID-19 within the first 5 days of symptom onset.

User Instructions

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 indicated.
2. Read this product insert completely before performing the test and follow the instructions carefully to avoid inaccurate results.
3. In vitro diagnostic use only.
4. Use only the components of this test kit. Do not mix components from different kits.
5. Do not use on anyone under 2 years of age.
6. Test Strip only: Do not use with multiple specimens.
7. Do not use test if the expiration date has passed.
8. Do not use test if the test strip is damaged or torn.
9. Do not dilute any component of the test kit.
10. Do not use if the solution in the tube is cloudy or discolored.
11. Do not use if the test strip is not clearly visible.
12. Do not use the test strip if the control line is not visible in 24 minutes.
13. Do not use if any component of test strip is not visible in 5 minutes.
14. Wash hands thoroughly or use hand sanitizer after handling.
15. Dispose of kit contents and patient samples in household trash.
16. Avoid handling the results window (i.e., membrane) of the Test Strips to minimize contamination.
17. Do not touch any part of the test kit contents, except the solution in the tube (sample buffer) and the test strip. Do not handle the test strip longer than 1 minute.
18. Do not put any component of the test kit in the mouth.
19. Do not place or store this product under light other than normal room lighting.
20. Do not use test on anyone under 2 years of age.
21. Do not use test if the expiration date has passed.
22. Do not perform the test if the test strip is damaged or torn.
23. Do not perform the test if the sample has been heated.
24. Do not use test on anyone under 2 years of age.
25. Do not use test if the expiration date has passed.
26. Do not use test if the test strip is damaged or torn.
27. Do not use test if the sample has been heated.
28. Do not use test on anyone under 2 years of age.
29. The control line may show up within a few minutes of starting the test. It may take up to 10 minutes for the test to complete.
30. Do not use test if the solution in the tube is cloudy or discolored.
31. Do not ingest any kit contents.
32. Use of this product is limited to individuals who are 18 years of age or older.

Warnings, Precautions and Safety

32. Use of this product is limited to individuals who are 18 years of age or older.
33. Use the test kit once only. Do not use with multiple specimens.
34. Use the test kit once only. Do not use with multiple specimens.
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90. Use the test kit once only. Do not use with multiple specimens.

How to perform the test

1. Fill out the patient information form and return it to your healthcare provider. The test kit is available at no cost to the patient.
2. Prepare the test kit by removing the test strip from the pouch and placing it on a clean, flat surface.
3. Open the test tube by removing the cap and setting it aside.
4. Remove the swab from the package and discard the package and any other components that are not required.
5. Hold the swab by the handle and insert the swab into the tube until it is completely submerged.
6. Gently mix the sample and the buffer by swirling the tube for at least 2 minutes.
7. Place the tube in the test strip and allow the sample to incubate for at least 5 minutes.
8. Carefully remove the test strip from the tube and lay it flat on a clean, flat surface.
9. Observe the results by looking at the test strip. The test will be positive if the control line is visible and the test line is visible.
10. If the test is positive, contact your healthcare provider to discuss your results.
11. If the test is negative, you may continue to isolate at home or seek additional testing.
12. Dispose of the test strip and any other components that are not required.

How to interpret the results

1. A negative result means that proteins from the virus that causes COVID-19 were not found in your sample and it is very likely you currently have COVID-19. If you test positive you should seek isolation 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/2019-ncov/symptoms-testing/symptoms.html.
2. 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 seek isolation 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/2019-ncov/symptoms-testing/symptoms.html.

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 your health. 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.

Serious Testing Information and Limitations

Serum samples are not recommended for the COVID-19 Antigen Home Test. Testing for COVID-19 with serum samples is not recommended due to the presence of antibodies that can interfere with test results.

Storage and Stability

Store the MaximBio ClearDetect™ COVID-19 Antigen Home Test Kit between 4°C - 30°C (39°F - 86°F). Ensure all 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.

Symptoms

For technical support: (P) 202-494-2300 tech@maximbio.com
(Available hours: Mon. to Fri. 9 a.m. - 4 p.m. EST)

MaximBio, Inc.
1500 East Drive
Rockville, MD 20850
www.maximbio.com
For use under the FDA Emergency Use Authorization (EUA) only.

Contents:
1 Nasal Swab
1 Test Strip
1 Sample Buffer Tube
1 User Instructions

301-251-0800
www.maximbio.com

TM

COVID-19 Antigen Home Test
For use under the FDA Emergency Use Authorization (EUA) only.

TM

EASY Nasal Swab Test
FAST Results in 15 min

TM

COVID-19 Antigen Home Test
For use under the FDA Emergency Use Authorization (EUA) only.
For use under the FDA Emergency Use Authorization (EUA) only.

Contents:
- 4 Nasal Swabs
- 4 Test Strips
- 4 Sample Buffer Tubes
- 1 User Instructions

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 exist justifying the authorization of the emergency use of medical devices 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. 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 first 5 days of symptom onset or those 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.

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 over two days. This test is not as sensitive as a lab-based molecular test. This test does NOT determine if you had COVID-19 in the past or if you have immunity.
Antigen Home Test

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

EASY Nasal Swab Test

FAST Results in 15 min

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 first 5 days of symptom onset or those 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.

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 (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. 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

Ages 2 and up