Test Procedure (Cont’d)

1. 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.

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

3. Swab Both Nostrils
   Gently insert the swab tip into one nostril about 1/2 to ¾ of an inch. Do not insert the swab any farther 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.

4. 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.

5. 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.
   Note: this step is very important, do not mix for less than 30 seconds.

6. 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.

7. 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.

8. 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.

9. 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.

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.

No Line
All used components should be disposed of in household trash.

Note: 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.

Note: This kit comes in 1, 2, 4, and 25 test quantities. The number of items supplied in the kit will vary depending on which kit is purchased.

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.

Test Procedure

1. 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.

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

3. Swab Both Nostrils
   Gently insert the swab tip into one nostril about 1/2 to ¾ of an inch. Do not insert the swab any farther 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.

4. 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.

5. 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.
   Note: this step is very important, do not mix for less than 30 seconds.

6. 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.

7. 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.

8. 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.

9. 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.

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.

No Line
All used components should be disposed of in household trash.

Note: 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.

Note: This kit comes in 1, 2, 4, and 25 test quantities. The number of items supplied in the kit will vary depending on which kit is purchased.

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.

Test Procedure

1. 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.

2. Open Swab
   Do not touch the swab tip.
   Open the swab packaging at stick end. Take out swab.
**User Instructions**

For Emergency Use Authorization (EUA) Only. In vitro diagnostic use only.

**How to Use This Test (Cont’d)**

- If you test negative but continue to have symptoms of COVID-19, and both your first and second tests are negative, you may not have COVID-19; however you should follow-up with your healthcare provider.
- If your test is positive, then proteins from the virus that causes COVID-19 have been found in your sample and you likely have COVID-19.

**Intended Use**

The MaximBio ClearDetect™ COVID-19 Antigen Home Test is a lateral flow immunochromatographic test intended for the qualitative detection of the nucleocapsid protein antigen from the SARS-CoV-2 virus.

This test is intended for use as a serial testing tool used for testing a household home with self-collected anterior nasal (nares) swab samples from individuals aged 14 or older and adults collected anterior nasal (nares) swab samples from individuals aged 2 or younger. 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 with symptoms of COVID-19 within 48 hours of symptom onset 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-2 or SARS-CoV-2.

**Warnings, Precautions and Safety**

- Read all instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate test results.

- 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 this test by FDA under an Emergency Use Authorization. This authorization allows FDA to authorize the use of emergency use of this test by FDA under an Emergency Use Authorization.

- **Serial testing should be performed in individuals with negative results at least twice over three days with at least 48 hours between tests** for symptomatic individuals and for individuals with symptoms of COVID-19 within 48 hours of symptom onset to suspect COVID-19, when tested at least three times over five days with at least 48 hours between tests.

**What is the difference between an antigen and molecular test?**

Antigen tests detect viral proteins, while molecular tests detect viral RNA. Antigen tests are generally faster and easier to perform but may miss some cases. Molecular tests are more sensitive and detect all cases, but take longer and are more complex.

**Frequently Asked Questions (Cont’d)**

- **How is this test performed?**
  - Serial testing should be performed in all individuals with negative results; individuals with symptoms of COVID-19 and initial negative results should be tested again after 48 hours. Individuals with negative results, should be tested again after 48 hours and, if the 2nd test is also negative, a 3rd test should be performed after an additional 48 hours. You may need to purchase additional tests to perform this serial (repeat) testing.

- **What if I have a positive test result?**
  - A positive test result indicates that the virus that causes COVID-19 was found in your sample. You should self- isolate from others and contact a healthcare provider for medical advice about your positive result.

- **What if I have a negative test result?**
  - A negative test result indicates that the virus that causes COVID-19 was not detected in your sample. However, if you have symptoms of COVID-19, and your first test is negative, you should test again in 48 hours since antigen tests are not as sensitive as molecular tests. If you do not have any symptoms and received a negative result, you should test at least two more times with at least 48 hours between each of those three tests. If you have a negative result, it does not rule out SARS-CoV-2 infection, you may still be infected and you may still infect others. It is important that you work with your healthcare provider to help you understand the next steps you should take.

- **What is an invalid result mean?**
  - 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 you should test again with a new test.

**Important**

- Do not use the test as the only guide to manage your illness. Consult your healthcare provider if your symptoms persist or become more severe.

**Storage and Stability**

Store the MaximBio ClearDetect™ COVID-19 Antigen Home Test Kit between 4-30°C (39-86°F). Ensure all kits are at room temperature before use. Kit contents are stable until the expiration date printed on the outer packaging. Do not use if the kit is past the expiration date.

**Frequent Asked Questions**

- **What are the known and potential risks and benefits of this test?**
  - **Potential benefits include:**
    - Possible discount during sample collection.
    - Possible incorrect test results (see Warnings and Rationale Interpretation sections for more information).

**Symbols**

- Catalog Number
- Lot Number (Batch Code)
- Use by (Expiration Date)
- Temperature Limitations
- One Time Use (Single Use Only)
- Manufacturer
- Date of Manufacture
- Consult Instructions for Use

**For technical support: (P) 301-251-0880; clarkmaxbio@maximbios.com**

**MaximBio**

**1500 East Gadsen Drive**

Riverview, FL 33569

www.maximbios.com

**Available hours**

Mon. to Fri.: 9 a.m. – 4 p.m. EST

**Number: LN-201510**

Effective Date: 2023-02-05
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 exists 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.

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either ISO at the address.

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

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

For Emergency Use Authorization (EUA) only

For symbol glossary, please refer to Instructions for Use

TM

For emergency use only. 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 exists 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.

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either ISO at the address.

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

2 Tests

EASY Nasal Swab Test

FAST Results in 15 min

Ages 2 and up

Items necessary but not included:
- Timer
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 exists 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.

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either ISO at the address.

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

4 Tests

EASY Nasal Swab Test

Results in 15 min

For Emergency Use Authorization (EUA) only

For symbol glossary, please refer to Instructions for Use

TM

Ages 2 and up

Items necessary but not included:

• Timer

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