ClearDetect™

COVID-19 Antigen Home Test

MaximBio

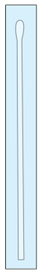
User Instructions

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

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

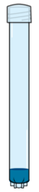
Kit Contents

Required testing components:



1 Swab

1 Test Strip in Pouch



1 Tube of Sample Buffer

Timer (not included)

Check printed Expiration Date

Note: This kit comits 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

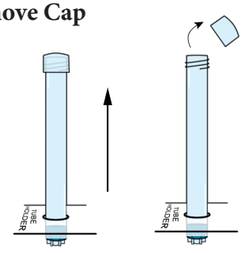
Check the test expiration (⧖) printed on the kit box. Wash or sanitize your hands. Make sure they are dry before starting. Ensure space is clean prior to testing.

Test Procedure

1 Stand Up Tube & Remove Cap

Place the tube upright in the tube holder/stand.

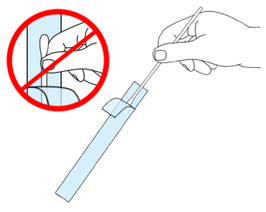
Remove cap - DO NOT discard. Save the cap for use in Step 9.



2 Open Swab

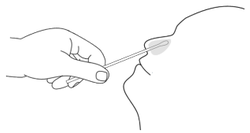
Do not touch the swab tip

Open the swab packaging at stick end. Take out swab.



Test Procedure (Cont'd)

3 Swab Both Nostrils



Gently insert the swab tip into one nostril about ½ 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.

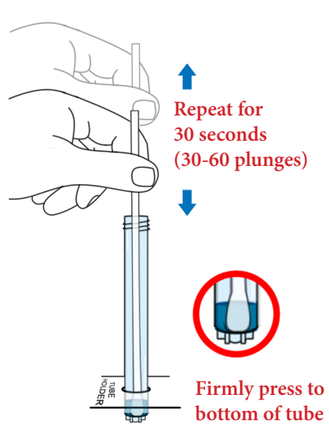
4 Swab Other Nostril

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.

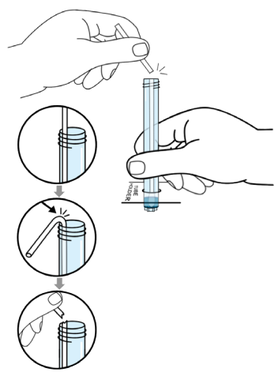


Note: this step is very important, do not mix for less than 30 seconds.

Note: Incorrect or invalid results may occur if the mix time is too short.

6 Break Swab

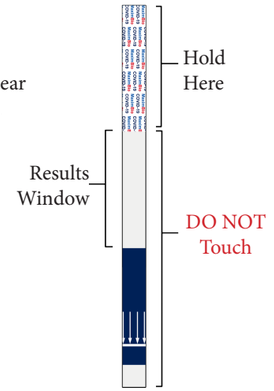
Make sure the swab tip is in the liquid inside of the tube. While using one hand to securely hold the tube down, use the other hand to carefully break the swab handle against the side of the tube. Discard the swab handle and leave the broken swab tip in the tube.

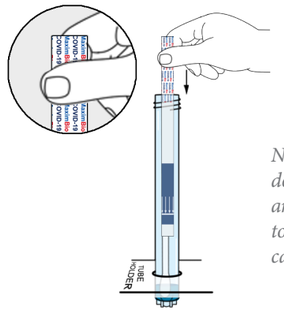


7 Insert Test Strip

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.



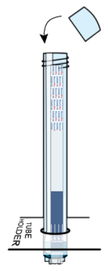


Note: If test strip is inserted upside down, discard all test components and restart from Step 1. Do not touch results window as it can cause false results.

8 Securely Cap the Tube

Keep tube UPRIGHT during entire test.

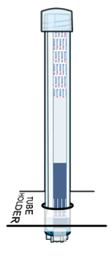
Make sure the test strip touches the bottom of the tube. While keeping the tube upright, secure the cap on the tube.

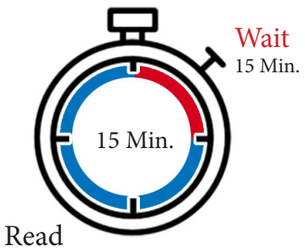


9 Wait 15 Minutes

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.

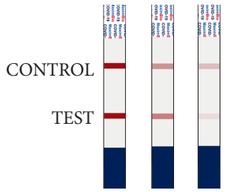




Note: False results may occur if the test is read outside the recommended time period. When reading test results, remove the test strip from the tube if necessary.

Interpret the Results

COVID-19 Positive (+)

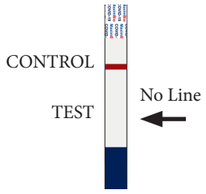


Look very closely!

Even a ***very faint***, pink Test Line and Control Line is a **POSITIVE** result. Any red/pink line here is 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 (-)

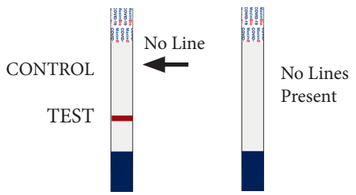


If the Control (C) line is visible, but the Test (T) line is not visible, the test is negative. **To increase the chance that the negative result for COVID-19 is accurate, you should:**

- **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.

Dispose In Trash

All used components should be disposed of in household trash.

MaximBio

ClearDetect™ COVID-19 Antigen Home Test

User Instructions

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

Interpret the Results (Cont'd)

Repeat testing is needed to improve test accuracy. Please follow the table below when interpreting test results for COVID-19.

Status on First Day of Testing	First Result Day 1	Second Result Day 3	Third Result Day 5	Interpretation
With Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	N/A	Negative for COVID-19
Without Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	Positive	Positive for COVID-19
	Negative	Negative	Negative	Negative for COVID-19

Results should be considered in the context of an individual's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19.

Report your test result(s) at MakeMyTestCount.Org - this voluntary and anonymous reporting helps public health teams understand COVID-19 spread in your area and across the country and informs public health decisions.

How to Use This Test

- 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 without symptoms of COVID-19, and with initial negative results, should be tested again after 48 hours and, if the 2nd test is also negative, a 3rd time after an additional 48 hours. You may need to purchase additional tests to perform this serial (repeat) testing.

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 immunoassay device intended for the qualitative detection of nucleocapsid protein antigen from the SARS-CoV-2 virus.
This test is authorized for non-prescription home use with self-collected anterior nasal (nares) swab samples from individuals aged 14 or older or adult collected anterior nasal (nares) swab samples from individuals aged 2 years or older. 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.
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 antigen, which is generally detectable in anterior nasal (nares) samples 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 definitive 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.
All negative results are 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 measures such as isolating from others and wearing masks. Negative results should be considered in the context of an individual's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19.
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 and to receive appropriate medical care. 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 intended for non-prescription self-use and/or as applicable, for an adult lay user testing another aged 2 years or older in a non-laboratory setting. The MaximBio ClearDetect™ COVID-19 Antigen Home Test is only for in vitro diagnostic use under the Food and Drug Administration's Emergency Use Authorization. This product has not been FDA cleared or approved.

Limitations

- There is a higher chance of false negative results with antigen tests than with laboratory-based molecular tests due to the sensitivity of the test technology. This means that there is a higher chance this test will give a false negative result in an individual with COVID-19 as compared to a molecular test, especially in samples with low viral load.
- The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between October, 2021 and December, 2021. The clinical performance has not been established for all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.
- All COVID-19 antigen test negative results are presumptive and confirmation with a molecular assay may be necessary. If you 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 a healthcare provider.
- If the test is positive, then proteins from the virus that causes COVID-19 have been found in the sample and you likely have COVID-19.
- This test is read visually and has not been validated for use by those with impaired vision or color-impaired vision.
- Incorrect test results may occur if a specimen is incorrectly collected or handled.

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 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.
- **Serial testing should be performed in individuals with negative results at least twice over three days (with 48 hours between tests) for symptomatic individuals and three times over five days (with at least 48 hours between tests) for asymptomatic individuals. You may need to purchase additional tests to perform this serial (repeat) testing.**
- If you have had symptoms longer than 5 days you should consider testing at least three times over five days with at least 48 hours between tests.
- An anterior nasal swab sample can be self-collected by an individual age 14 years and older. Children age 2 to 13 years should be tested by an adult.
- Do not use on anyone under 2 years of age.
- Wear a safety mask or other face-covering when collecting a specimen from a child or another individual.
- Do not use if any of the test kit contents or packaging is damaged.
- Test components are single-use. Do not re-use.
- Do not use kit past its expiration date.
- Do not touch the swab tip.
- Once opened, the test strip should be used within 5 minutes.
- Do not read test results before 15 minutes or after 30 minutes. Results read before 15 minutes or after 30 minutes may lead to a false positive, false negative, or invalid result.
- Keep testing kit and kit components away from children and pets before and after use. Avoid contact with your skin, eyes, nose, or mouth. Do not ingest any kit components. The reagent solution contains harmful chemicals (see table below). If the solution contacts your skin, eyes, nose, or mouth, flush with large amounts of water.
- If irritation persists, seek medical advice: https://www.poisonhelp.org or 1-800-222-1222.

Chemical Name	GHS Code for each Ingredient	Concentrations
Microcide III	H317, May cause an allergic skin reaction H320 , Causes eye irritation H316, Causes mild skin irritation	0.2%
Tris Base	H320 , Causes eye irritation H316, Causes mild skin irritation	0.242%
Sodium chloride	H320 , Causes eye irritation	1.75%
Tris-HCl	H320 , Causes eye irritation H316, Causes mild skin irritation	0.314%
NP-40	H316, Causes mild skin irritation	0.6%

- For more information on EUAs please visit: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization
- For the most up to date information on COVID-19, please visit: www.cdc.gov/COVID19

Frequently Asked Questions

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 Warnings and Result Interpretation sections for more information).

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.

For more information on EUAs go here: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization

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. 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.

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 virus 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 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 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 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 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 symptoms and received a negative result, you should test at least two more times with 48 hours in between tests for a total of 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 does an invalid test 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 this test as the only guide to manage your illness. Consult your healthcare provider if your symptoms persist or become more severe.

Individuals should provide all results obtained with this product to their healthcare provider.

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. For the most current expiration dates of this test, please refer to: http//www.fda.gov/covid-tests.

Symbols

REF	Catalog Number	IVD	In vitro diagnostic use only
LOT	Lot Number (Batch Code)	Σ	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

Maxim Biomedical, Inc.
1500 East Gude Drive
Rockville, MD 20850
www.maximbio.com

For technical support:
(P) 301-251-0800
cleardetect@maximbio.com

Available hours:
Mon. to Fri.:
9 a.m. – 4 p.m. EST

Number: LN-20615.10 Effective Date: 2023-09

MaximBio

ClearDetect™

COVID-19

Antigen Home Test

1 Test

MaximBio

ClearDetect™

COVID-19

Antigen Home Test

For Emergency Use Authorization (EUA) only

Ages 2 and up

For symbol glossary, please refer to Instructions for Use

Contents:

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

Items necessary but not included:

- Timer

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

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.

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.

MaximBio

ClearDetect™

COVID-19

Antigen Home Test

MaximBio

4°C 30°C

IVD

REF 94311

FPO

MaximBio

ClearDetect™

COVID-19

EASY
Nasal Swab Test

FAST
Results in **15** min

MaximBio
ClearDetect™
COVID-19

15:00

Results

EASY
Nasal Swab Test

FAST
Results in **15** min

11.5938

12.2074

MaximBio

2
Tests

MaximBio

CLEARDETECT™

COVID-19

Antigen Home Test

2
Tests

MaximBio

CLEARDETECT™

COVID-19

Antigen Home Test

For Emergency Use Authorization (EUA) only

MaximBio

CLEARDETECT™

COVID-19

Antigen Home Test

Ages 2 and up

For Emergency Use Authorization (EUA) only

Contents:

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

Items necessary but not included:

- Timer

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

For symbol glossary, please refer to Instructions for Use

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.

MaximBio

CLEARDETECT™

COVID-19

Antigen Home Test

MaximBio

4°C
30°C
IVD
REF 95677

8 69978 00004 3

MaximBio

CLEARDETECT™

COVID-19

EASY
Nasal Swab Test

FAST
Results in **15** min

MaximBio

CLEARDETECT™

COVID-19

15:00

Results

EASY
Nasal Swab Test

FAST
Results in **15** min

12.074"

12.598"

MaximBio

CLEARDETECT™

COVID-19

Antigen Home Test

4 Tests

MaximBio

CLEARDETECT™

COVID-19

Antigen Home Test

For Emergency Use Authorization (EUA) only

Ages 2 and up

Contents:

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

Items necessary but not included:

- Timer

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

For symbol glossary, please refer to Instructions for Use

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.

MaximBio

CLEARDETECT™

COVID-19

Antigen Home Test

MaximBio

4°C

30°C

IVD

REF 97382

8 69978 00006 7

MaximBio

CLEARDETECT™

COVID-19

EASY
Nasal Swab Test

FAST
Results in **15** min

MaximBio
CLEARDETECT™
COVID-19

15:00

Results

EASY
Nasal Swab Test

FAST
Results in **15** min

MaximBio

25 Tests

COVID-19

Antigen Home Test

For Emergency Use Authorization (EUA) only

Ages 2 and up

MaximBio

COVID-19

Antigen Home Test

Contents:

- 25 Nasal Swabs
- 25 Test Strips
- 25 Sample Buffer Tubes
- 1 User Instructions

Items necessary but not included:

- Timer

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

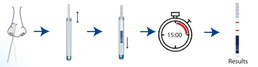
MaximBio

25 Tests

COVID-19

Antigen Home Test

For Emergency Use Authorization (EUA) only



MaximBio

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.

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.

For symbol glossary, please refer to Instructions for Use

25 Tests

MaximBio

COVID-19

Antigen Home Test

For Emergency Use Authorization (EUA) only

EASY
Nasal Swab Test

FAST
Results in 15 min

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

Antigen Home Test

MaximBio

9"

5.625″

9"

5.625″

3.75″