MaximBio

MaximBio ClearDetect™ COVID-19 Antigen Home Test

Healthcare Provider Instructions for Use (IFU)

For *in vitro diagnostic* Use Only
For use with anterior nasal swab specimens
For Emergency Use Authorization (EUA) Only

1. INTENDED USE

The MaximBio ClearDetect™ COVID-19 Antigen Home Test is a rapid lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2. This test is authorized for non-prescription home use with self-collected anterior 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 adult-collected anterior nasal (nares) samples from individuals aged 2 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 14 years or older, or adult-collected anterior nasal (nares) samples from individuals aged 2 or older, 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.

The MaximBio ClearDetect™ COVID-19 Antigen Home Test does not differentiate between SARS-CoV and SARS-CoV-2.

Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen. Antigen is generally detectable in anterior nasal (nares) swab specimens 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 definite 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.

Negative results should be treated as 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 decisions.

Negative results should be considered in the context of a patient's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19.

For serial testing programs, additional confirmatory testing with a molecular test for negative results may be necessary, if there is a high likelihood of SARS-CoV-2 infection, such as in an individual with a close contact with COVID-19 or with suspected exposure to COVID-19 or in communities with high prevalence of infection. Additional confirmatory testing with a molecular test for positive results may also be necessary, if there is a low likelihood of SARS-CoV-2 infection, such as in individuals without known exposures to COVID-19 or residing in communities with low prevalence of infection.

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. 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 authorized for non-prescription self-use and/or as applicable for an adult lay user testing another person 2 years or older. The MaximBio ClearDetect™ COVID-19 Antigen Home Test is only for use under the Food and Drug Administration's Emergency Use Authorization.

2. EXPLANATION OF THE TEST

COVID-19 (short for 'Coronavirus Disease 2019') is a disease first recognized in 2019 that is caused by a type of novel coronavirus called SARS-CoV-2. Due to its rapid spread, the World Health Organization (WHO) recognized the disease as a global pandemic on March 11, 2020. Individuals infected with SARS-CoV-2 may have a range of symptoms from asymptomatic infection to severe respiratory illness and even death. The virus is spread primarily from person to person through respiratory particles, even by individuals without symptoms.

The MaximBio ClearDetect™ COVID-19 Antigen Home Test is a rapid, qualitative immunochromatographic immunoassay for the determination of the presence of antigens from SARS-CoV-2 in direct anterior nasal swab specimens. The MaximBio ClearDetect™ COVID-19 Antigen Home Test Kit is comprised of a sample collection device (nasal swab), Sample Buffer Tube, and Test Strip. The Test Strip is composed of several materials which, in combination, can detect SARS-CoV-2 antigens.

The sample should be collected with the provided nasal swab. The swab containing the sample is then added directly into the Sample Buffer Tube containing Sample Buffer and mixed. The Test Strip is then added into the tube. The Sample Buffer and sample mixture is absorbed through the sample pad on the Test Strip to initiate the test run via capillary action. This sample mixture continues to migrate up the Test Strip by capillary action, until it rehydrates the red colored conjugate.

The sample mixture liquid will continue to move up the Test Strip across the nitrocellulose membrane containing two reagent lines, contacting the Test Line first and then the Control Line. If SARS-CoV-2 antigen is present in the sample, it will bind to the anti-SARS-CoV-2 conjugate particles and then be captured on the Test Line, forming a reddish pink line indicating a SARS-CoV-2 antigen positive test result. The sample mixture liquid will continue to move up the Test Strip and will bind to the Control Line, forming a reddish pink line, to indicate the test was run correctly and establishes assay validity. The Control Line will appear on all valid tests whether the Test Line gives a reactive or non-reactive result. If a red colored Control Line does not appear, the test is invalid, and the specimen must be retested. The liquid will continue to be drawn up to the absorbent pad of the Test Strip until the color on the membrane has cleared within 15 minutes after the start of the test.

The results of the test are interpreted at 15 minutes. Refer to the Interpretation of Results section.

3. MATERIALS AND REAGENTS PROVIDED

The MaximBio ClearDetect™ COVID-19 Antigen Home Test is offered in a 1, 2, 4 and 25 test/kit size. The kit configurations are provided below:

	Number of Test/Kit	1 Test/Kit	2 Tests/Kit	4 Tests/Kit	25 Tests/Kit
Reagent/ Material	MaximBio COVID-19 Test Strip	1	2	4	25
	Sample Buffer Tube	1	2	4	25
	Tube Stand	1	1	1	25
	Nasal Swab	1	2	4	25
	User Instructions	1	1	1	1

4. MATERIALS REQUIRED BUT NOT PROVIDED

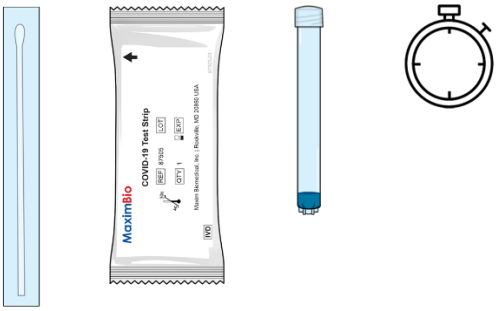
- Timer

5. QUALITY CONTROL

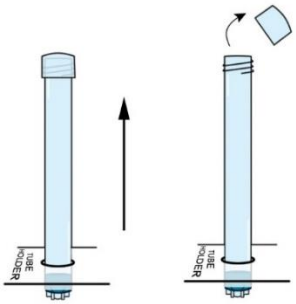
Each MaximBio ClearDetect™ COVID-19 Antigen Home Test has a built-in internal procedural control. The reddish pink line appearing at the “C” position is an internal procedural control. This procedural Control Line indicates that sufficient flow has occurred, and the functional integrity of the test device has been maintained. A distinct reddish pink Control Line should always appear if the test has been performed correctly. If the Control Line does not appear, the test result is invalid and a new test should be performed.

6. TEST PROCEDURES

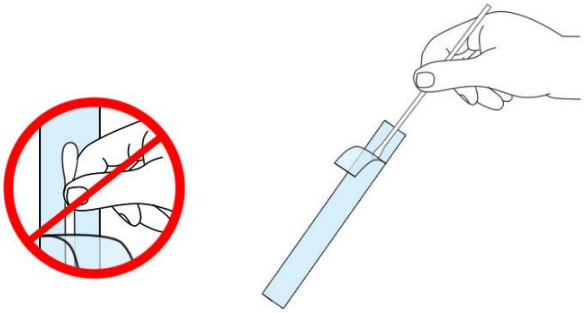
1. Check the test expiration printed on the kit box. Wash or sanitize your hands. Make sure they are dry before starting. Ensure space is clean prior to testing. Required testing components: 1 Swab, 1 Test Strip in Pouch, 1 Tube of Sample Buffer, Timer (not included).



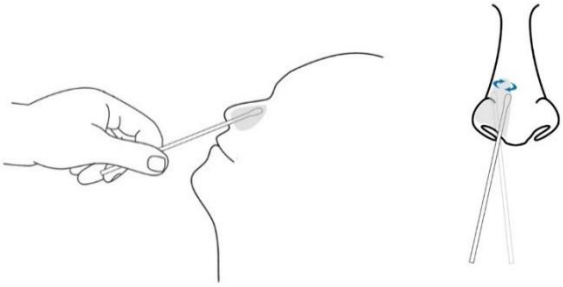
2. Place the tube upright in the tube holder/stand. Remove cap – DO NOT discard. Save the cap for use in Step 9.



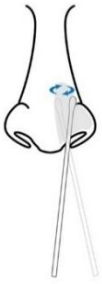
3. Do not touch the swab tip. Open the swab packaging at stick end. Take out swab.



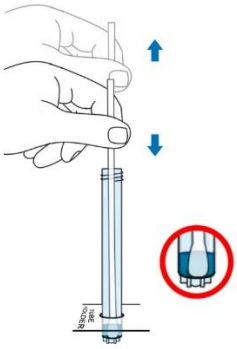
4. Gently insert the swab tip into one nostril about ½ to ¾ of an inch. Do not insert the swab any farther if you feel any resistance. Using medium pressure, rub the swab tip against the inside wall of the one nostril. Make at least 5 large circles (about 15 seconds). Do not just spin the swab.



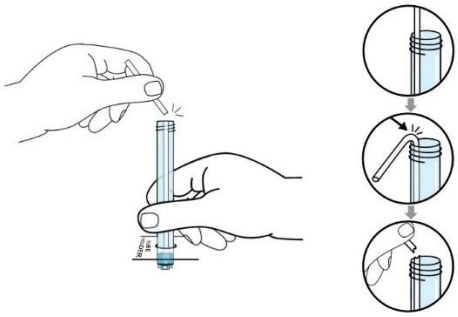
5. Using the same swab, repeat Step 4 in the other nostril.
Note: Both nostrils must be swabbed to ensure accurate results.
Note: If you are swabbing others, please wear a face mask. With children, you may not need to insert the swab as far into the nostril. For very young children, you may need another person to steady the child's head while swabbing.



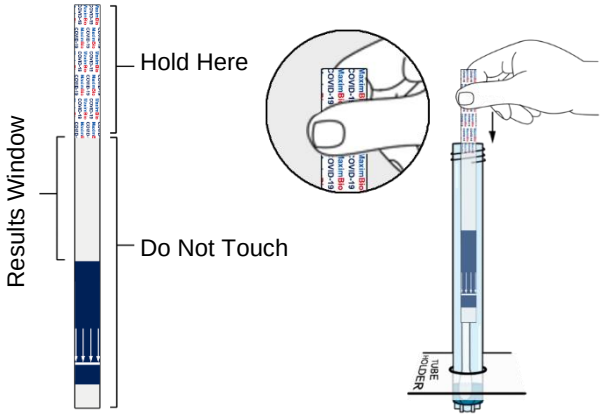
6. Completely submerge swab tip into the liquid inside the tube and set a 30 second timer. Repeatedly plunge for 30 seconds (approximately 30-60 plunges) or more. Mix by firmly pressing the swab tip to the bottom of the tube with each down motion. *Note: this step is very important, do not mix for less than 30 seconds. Note: Incorrect or invalid results may occur if the mix time is too short.*



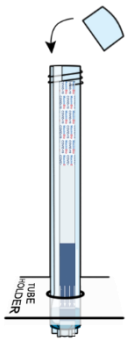
7. Make sure the swab tip is in the liquid inside of the tube. While using one hand to securely hold the tube down, use the other hand to carefully break the swab handle against the side of the tube. Discard the swab handle and leave the broken swab tip in the tube.



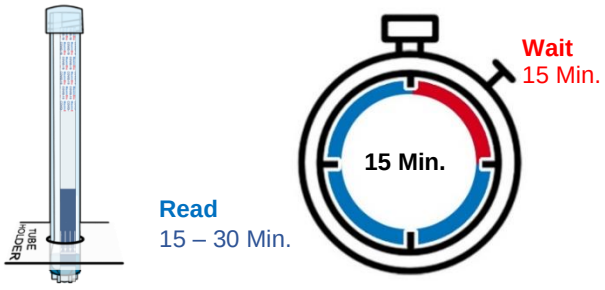
8. Open the test strip pouch carefully at tear notch and hold the test strip as shown. Hold the "MaximBio COVID-19" side of the test strip and carefully place it into the tube, facing outwards, so the results window is clearly visible. ***Note: If test strip is inserted upside down, discard all test components and restart from Step 1****. Do not touch results window as it can cause false results.*



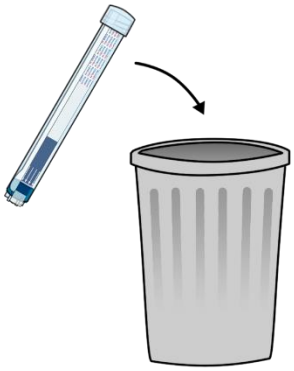
9. Keep tube UPRIGHT during entire test. Make sure the test strip touches the bottom of the tube. While keeping the tube upright, secure the cap on the tube.



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



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

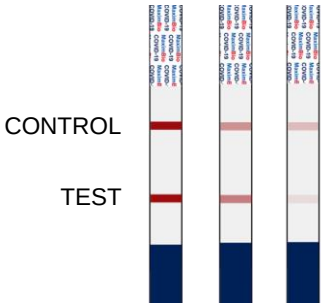


7. INTERPRETATION OF RESULTS

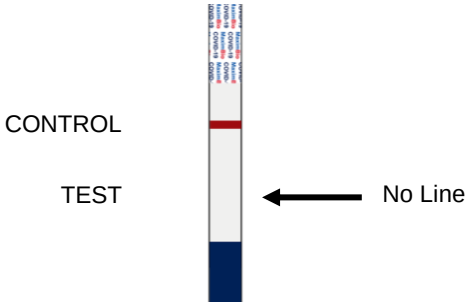
Test results are read and interpreted visually. Read results at 15 minutes with good lighting.
Do not read results before 15 minutes or after 30 minutes.

Check for Positive COVID-19 Result
Find the result area and look carefully for two red/pink lines.
Positive Result: If two red/pink lines appear, this means **COVID-19 was detected.**

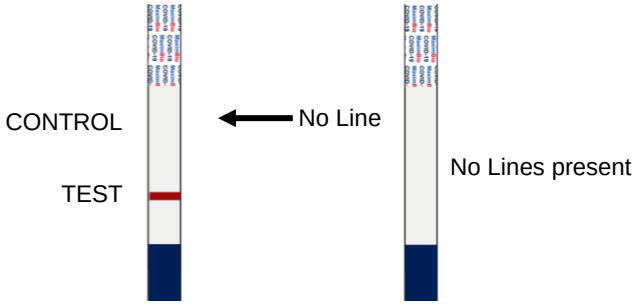
Look very closely! Even a very faint, pink Test Line and Control Line is a POSITIVE result. Any red/pink line is positive.



Check for Negative COVID-19 Result
Find the result area and look carefully for a single red/pink line.
Negative Result: A single red/pink line on the upper half toward where it says “MaximBio COVID-19”. **COVID-19 was not detected**.



Check for Invalid COVID-19 Result
If you see a test line only with no control or no lines at all, the test is invalid. If results are invalid, perform entire process again starting from step 1 using all new kit components.
If results are invalid again after retesting, please call technical support.



What Your Results Mean
Positive Result
If a Control I line and the Test (T) line are visible, the test is positive. Any faint visible reddish pink test (T) line with the control line I 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.

Negative Result
If the Control I 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 above the limit of detection 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 of 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.

Invalid Result

If a control I line is not visible, even if a test line is visible, the test is invalid. An invalid result means this test was unable to determine whether you have COVID-19 or not. You may have performed the test incorrectly. Carefully read the Instructions for Use and re-test. Collect a new sample and perform the test again with a new device and new tube. If the test is still invalid, contact technical support for assistance.

8. STORAGE AND STABILITY

Store the MaximBio ClearDetect™ COVID-19 Antigen Home Test between 4-30°C (39.2-86°F). Ensure all kit components are at room temperature before use. Kit components 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 foil pouch until use.

9. WARNINGS AND PRECAUTIONS

1. This product has not been FDA cleared or approved, but has been authorized by FDA under an EUA;
2. This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens; and
3. 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.
4. Follow instructions for use.
5. This test is intended to aid in a diagnosis of a current SARS-CoV-2 infection, not for any other viruses or pathogens.
6. Read this product insert completely before performing the test and follow the instructions carefully to avoid obtaining inaccurate results.
7. Use of personal protection materials such as gloves is recommended.
8. You should wear a face mask if swabbing others.
9. Use only the components of this test kit.
10. All kit components are intended for single use. Do not use with multiple specimens. Do not reuse the used Test Strip.
11. Laboratories within the United States and its territories are required to report results to the appropriate public health authorities.
12. This test is intended as an aid in the diagnosis of COVID-19 by detecting viral antigens but should not be used as a sole criterion for the determination of SARS-CoV-2 infection. Other laboratory tests and clinical information (signs and symptoms) should be used and considered for diagnosis.
13. Do not open the Test Strip pouch packaging until ready to perform a test. Use immediately.
14. MaximBio ClearDetect™ COVID-19 Antigen Home Test should be performed at ambient temperature (i.e., 15-30°C).
15. Test Strips and sample collection devices are intended for a single use. Do not use more than once. If a test must be repeated, use new components for the retest.
16. Do not use kit past the expiration date printed.
17. Do not use if the pouch is damaged or open.
18. Do not use nasal sprays for at least 30 minutes before collecting a nasal sample.
19. Inadequate or inappropriate sample collection may yield false test results.
20. Proper specimen collection and handling are essential for accurate results.
21. Do not touch swab head (specimen collection area) while handling the swab.
22. Do not use on anyone who is prone to nosebleeds or who has had facial injuries or head injuries/surgery in the past six months.
23. If you suspect the presence of blood on the swab, discard the swab, make sure you are not bleeding, and repeat with a fresh one.
24. Ensure Test Strip remains upright throughout the duration of the test. Improper handling and setup may yield inaccurate results.
25. Avoid handling the results window area (i.e., membrane) of the Test Strips to minimize contamination.
26. The control line may show up within a few minutes of starting the test. It may take up to 15 minutes for a test line to show up.

27. Be sure to read test result after 15 minutes. Do not read results after 30 minutes. If the test is read before 15 minutes or after 30 minutes, false negative or false positive results may occur, and the test should be repeated with a new test device.
28. After performing the test, read the Test Strip results visually in a brightly lit area to ensure accurate interpretation.
29. Make sure there is sufficient light when testing.
30. This test is read visually. Users with impaired vision or with color-impaired vision may not be able to adequately interpret test results.
31. In the event of spillage, ensure it is cleaned thoroughly using a suitable disinfectant.
32. Do not ingest any kit components.
33. Keep test kit and components out of the reach of children and pets before and after use.
34. Wash hands thoroughly or use hand sanitizer after handling.
35. Dispose of kit components and patient samples in household trash.
36. Avoid contact with skin and eyes.
37. The chemicals in the reagent solution may be hazardous to the skin and eye. Please see the table below for safety recommendations for skin and eye irritation. Use of gloves is recommended when conducting testing.

Hazard Category (mixture)	GHS Hazard Statement for mixture	Labeling of Harm(s)	Hazardous Ingredients (%)	Recommended PPE Statement
Category 1	Skin sensitization	May cause an allergic skin reaction (H317)	Microcide III (0.2%)	Gloves
Category 2	Eye irritation	Causes eye irritation (H320)	Tris Base (0.242%) Tris-HCl (0.314%) Sodium chloride (1.75%) NP-40 (0.6%) Microcide III (0.2%)	NA
Category 3	Skin irritation	Causes mild skin irritation (H316)	Tris Base (0.242%) Tris-HCl (0.314%) NP-40 (0.6%) Microcide III (0.2%)	NA

38. If the reagent contacts the skin or eye, flush with plenty of water. If irritation persists, seek medical advice. https://www.poison.org/contact-us or 1-800-222-1222.

10. LIMITATIONS

- Do not use on anyone under 2 years old.
- Children aged 2-13 years should be tested by an adult.
- This device is only used for testing direct human anterior nasal swab specimens. Viral transport media (VTM) should not be used with this test.
- Testing for asymptomatic individuals should be performed at least twice over three days, with at least 24 hours and no more than 48 hours between tests. You may need to purchase additional tests to perform this serial (repeat) testing.
- There is a higher chance of false negative results with home use tests than with laboratory-based molecular tests. This means that there is a higher chance this test will give you a negative result when you have COVID-19.
- Serial testing (i.e., testing every day or every other day) is more likely to detect COVID-19, especially when you do not have any symptoms.
- The test detects both viable (live) and nonviable SARS-CoV-2. Test performance depends on the amount of virus (antigens) in the sample and may or may not correlate with viral culture results performed on the same sample.
- A negative test result may occur if the level of antigen in the sample is below the detection limit of the test or if the sample was collected improperly.
- Failure to follow the test procedure correctly may results in false negative or false positives results and/or invalidate the test result.
- Test results must be evaluated in conjunction with other clinical data available to the physician.
- Positive test results do not exclude co-infection with other pathogens.
- Negative test results are not indicative of the presence/absence of other viral or bacterial pathogens.
- Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.
- Negative results should be treated as presumptive and confirmed with an FDA-authorized molecular assay, if necessary, for clinical management.
- Performance of nasal swabs collected from patients without symptoms or other epidemiological reasons to suspect COVID-19 infection or for serial screening, when tested twice over two to three days with at least 24 but not more than 48 hours between tests has not yet been determined; a study to support use will be completed.
- If the differentiation of specific coronaviruses and strains is needed, additional testing, in consultation with state or local public health departments, is required.
- The amount of antigen in a sample may decrease as the duration of illness increases. Specimens collected after seven days are more likely to be negative compared to RT-PCR.
- The performance of the COVID-19 At-Home Test was evaluated using the procedures provided in these Instructions for Use (IFU) only. Modifications to these procedures may alter the performance of the test.
- The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between October and December 2021. The clinical performance has not been established in 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.

11. PERFORMANCE CHARACTERISTICS

Limit of Detection (LOD)

The LOD of the MaximBio ClearDetect™ COVID-19 Antigen Home Test was established by using limiting dilutions of heat inactivated SARS-CoV-2 virus (USA_WA1/2020). Dilutions of the heat inactivated SARS-CoV-2 virus were created by mixing the stock culture fluid into clinical nasal fluid.

The estimated LOD was found from the initial 6 different concentrations test by testing 5 replicates. At each dilution, samples were added to swabs and then tested through the full assay workflow.

An initial LOD concentration was chosen and determined as the lowest virus concentration that was detected ≥ 95% of the time (concentration at which at least 19 out of 20 replicates tested positive).

The MaximBio ClearDetect™ COVID-19 Antigen Home Test LOD was determined to be 750 $TCID_{50}$/mL.

The performance of this test device in the detection of the Omicron variant of SARS-CoV-2 was evaluated in a dilution series of clinical specimens which were positive for the Omicron variant. This testing was conducted by the National Institutes of Health (NIH) as a component of the Rapid Acceleration of Diagnostics (RADx®) initiative. The clinical specimens used to prepare this dilution series were not identical to the previous specimen pools prepared and tested by RADx to assess performance with the omicron variant. Results from this dilution series cannot be compared to other specimen pools and do not indicate that a test will have different clinical performance compared to other EUA authorized tests. Compared to an EUA authorized RT-PCR method, the MaximBio ClearDetect™ COVID-19 Antigen Home Test detected 100% of live virus Omicron samples at a Ct-value of 25.8 (n=5). Testing was also compared to two additional EUA-authorized OTC antigen tests (Assay #1 and Assay #2). Omicron dilutions at lower viral concentrations (Ct-values greater than 27.4) were not detected by the MaximBio ClearDetect™ COVID-19 Antigen Home Test in this study.

Omicron Pool 2 – Live Omicron Clinical Samples	Average N2 Ct (n=9)	Assay #1 Percent Positive (n=5)	Assay #2 Percent Positive (n=5)	MaximBio ClearDetect™ Percent Positive (n=5)
Omicron-Dilution 1	19.8	100	100	100
Omicron-Dilution 2	20.8	100	100	100
Omicron-Dilution 3	21.5	100	100	100
Omicron-Dilution 4	22.7	100	100	100
Omicron-Dilution 5	23.6	100	0	100
Omicron-Dilution 6	24.0	60	0	100
Omicron-Dilution 7	24.8	0	0	100
Omicron-Dilution 8	25.8	0	0	100
Omicron-Dilution 9	27.4	0	0	0
Omicron-Dilution 10	28.1	0	0	0
Omicron-Dilution 11	29.1	0	0	0

Cross Reactivity (Analytical Specificity) and Microbial Interference

The potential cross-reactivity (analytical specificity) and microbial interference of common organisms were evaluated using the MaximBio ClearDetect™ COVID-19 Antigen Home Test.

Thirty-three (33) pathogens (bacteria, viruses, and fungi) were evaluated for their ability to cause false positive results at concentrations comparable to or greater than levels that may be present in respiratory samples. Each of the organisms and viruses were tested in triplicate for the absence or presence of heat inactivated SARS-CoV-2 virus.

No cross-reactivity or interference was observed with the following microorganisms when tested at the concentration presented in the table below.

Organism	Conc. Tested	Units	Cross-reactivity results	Microbial Interference results
Human coronavirus 229E	1.4×10^6	$TCID_{50}$/mL	No cross-reactivity	No interference
Human coronavirus OC43	4.45×10^6	$TCID_{50}$/mL	No cross-reactivity	No interference
Human coronavirus NL63	1.41×10^5	$TCID_{50}$/mL	No cross-reactivity	No interference
SARS-coronavirus	1.0×10^8	PFU/mL	Cross-reactivity observed	Not Tested
MERS-coronavirus	8.9×10^5	$TCID_{50}$/mL	No cross-reactivity	No interference
Adenovirus 1	4.45×10^6	$TCID_{50}$/mL	No cross-reactivity	No interference
Human Metapheumovirus	1.9×10^6	$TCID_{50}$/mL	No cross-reactivity	No interference
Parainfluenza virus 1	6.3×10^5	$TCID_{50}$/mL	No cross-reactivity	No interference
Parainfluenza virus 2	1.4×10^6	$TCID_{50}$/mL	No cross-reactivity	No interference
Parainfluenza virus 3	1.4×10^7	$TCID_{50}$/mL	No cross-reactivity	No interference
Parainfluenza virus 4a	5.75×10^6	$TCID_{50}$/mL	No cross-reactivity	No interference
Parainfluenza virus 4b	5.01×10^5	$TCID_{50}$/mL	No cross-reactivity	No interference
Influenza A – H1N1	2.6×10^7	$CEID_{50}$/mL	No cross-reactivity	No interference
Influenza A – H3N2	1.3×10^6	$TCID_{50}$/mL	No cross-reactivity	No interference
Influenza B – Victoria Lineage	1.1×10^8	$CEID_{50}$/mL	No cross-reactivity	No interference

Organism	Conc. Tested	Units	Cross-reactivity results	Microbial Interference results
Influenza B – Yamagata Lineage	6×10^7	$CEID_{50}$/mL	No cross-reactivity	No interference
Enterovirus 68	2×10^7	$TCID_{50}$/mL	No cross-reactivity	No interference
Respiratory syncytial virus Type A	1.26×10^6	$TCID_{50}$/mL	No cross-reactivity	No interference
Respiratory syncytial virus Type B (RSV-B)	1.05×10^6	U/mL	No cross-reactivity	No interference
Rhinovirus	4.45×10^7	$TCID_{50}$/mL	No cross-reactivity	No interference
Haemophilus influenzae	6×10^9	CFU/mL	No cross-reactivity	No interference
Streptococcus pneumoniae	2.25×10^7	CFU/mL	No cross-reactivity	No interference
Streptococcus pyogenes	1.5×10^8	CFU/mL	No cross-reactivity	No interference
Candida albicans	2.81×10^8	CFU/mL	No cross-reactivity	No interference
Bordetella pertussis-Tohama	5×10^9	CFU/mL	No cross-reactivity	No interference
Bordetella pertussis-Strain10-536	5×10^9	CFU/mL	No cross-reactivity	No interference
Mycoplasma pneumonia	5×10^8	CFU/mL	No cross-reactivity	No interference
Chlamydia pneumoniae	1.6×10^6	$TCID_{50}$/mL	No cross-reactivity	No interference
Chlamydia trachomatis	5.45×10^8	IFU/mL	No cross-reactivity	No interference
Legionella pneumophila	1.3×10^8	CFU/mL	No cross-reactivity	No interference
Staphylococcus aureus	4.6×10^6	CFU/mL	No cross-reactivity	No interference
Staphylococcus epidermidis	1.8×10^9	CFU/mL	No cross-reactivity	No interference

To estimate the likelihood of cross-reactivity with SARS-CoV-2 of organisms that were not available for wet testing, in-silico analysis using the Basic Local Alignment Search Tool (BLAST) managed by the National Center for Biotechnology Information (NCBI) was used to assess the degree of protein sequence homology. HKU1 nucleocapsid phosphoproteins, Mycobacterium tuberculosis, and Pneumocystis jirovecii (PJP) were analyzed and results are below.

- The homology between SARS-CoV-2 nucleocapsid protein and human coronavirus HKU1 nucleocapsid phosphoproteins is relatively low, at **36.74**% across **82**% of sequences, but cross-reactivity cannot be ruled out.
- No homologous protein sequence was found as a result of in-silico analysis with Mycobacterium tuberculosis total protein and SARS-CoV-2 nucleocapsid protein. Despite there being little homology observed, the cross-reactivity of the test against Mycobacterium tuberculosis cannot be ruled out.
- No homologous protein sequence was found as a result of in-silico analysis with Pneumocystis jirovecii (PJP) total protein and SARS-CoV-2 nucleocapsid protein. Despite there being little homology observed, the cross-reactivity of the test against Pneumocystis jirovecii (PJP) cannot be ruled out.

Endogenous Interfering Substances

The following substances, naturally present in respiratory specimens or that may be artificially introduced into the nasal cavity or nasopharynx, were evaluated with the MaximBio ClearDetect™ COVID-19 Antigen Home Test.

All samples tested in triplicate produced expected results, demonstrating that the MaximBio ClearDetect™ COVID-19 Antigen Home Test performance was not affected by any of the 21 potentially interfering substances listed in the table below at the concentrations tested.

Substance	Conc./Amount Used	Cross-Reactivity	Interference
Human Whole Blood (EDTA tube)	4%	No cross-reactivity	No interference
Mucin (porcin stomach, type II)	0.50%	No cross-reactivity	No interference
Chloraseptic (Menthol/Benzocaine)	1.5 mg/mL	No cross-reactivity	No interference
Naso GEL (NeilMed)	5% v/v	No cross-reactivity	No interference
Nasal Drops (Phenylephrine)	15% v/v	No cross-reactivity	No interference
Afrin (Oxymetazoline)	15% v/v	No cross-reactivity	No interference
Nasal Spray (Cromolyn)	15% v/v	No cross-reactivity	No interference
Zicam	5% v/v	No cross-reactivity	No interference
Homeopathic (Alkalol)	10% v/v	No cross-reactivity	No interference
Sore Thorat Phenol Spray	15% v/v	No cross-reactivity	No interference
Tobramycin	4 µg/mL	No cross-reactivity	No interference
Mupirocin	10 mg/mL	No cross-reactivity	No interference
Tamiflu (Oseltamivir Phosphate)	5 mg/mL	No cross-reactivity	No interference
Fluticasone Propionate	5% v/v	No cross-reactivity	No interference
Disinfectant Wipes (Alkyl C14 (50%), C12 (40%), C16 (10%) Dimethyl Benzyl Ammonium Chloride, 0.26%)	1 wipe	No cross-reactivity	No interference
Bleach Wipes (0.525% bleach)	1 wipe	No cross-reactivity	No interference
Hand Sanitizer Gel (70% ethyl alcohol)	1.038 g	No cross-reactivity	No interference
Hand Lotion	0.991 g	No cross-reactivity	No interference
Hand Lotion with Aloe	1.013 g	No cross-reactivity	No interference
Hand Lotion with Coconut Oil, Cocoa Butter, and African Shea Butter	1.067 g	No cross-reactivity	No interference
Hand Soap	1.055 g	No cross-reactivity	No interference

Hook Effect

No high dose hook effect was observed when tested with a concentration of 1.6×10^5 $TCID_{50}$/mL of heat inactivated SARS-CoV-2 virus with the MaximBio ClearDetect™ COVID-19 Antigen Home Test.

Flex study

The robust use of MaximBio ClearDetect™ COVID-19 Antigen Home Test was demonstrated by ten (10) Flex studies: Reading Time Analysis, Mix Duration and Method Analysis, Specimen Volume Analysis, Sample Buffer Volume Analysis**,** Temperature and Humidity System Analysis, Lighting Conditions Analysis**,** Operator Error/Human Factors Analysis**,** Specimen Stability (Specimen in Sample Buffer)**,** Specimen Stability (Dry Swab), and Sample Buffer Evaporation.

CLINICAL PERFORMANCE

A prospective study was completed at five (5) sites in the United States for clinical validation of the MaximBio ClearDetect™ COVID-19 Antigen Home Test for the detection of the SARS-CoV-2 in subject-collected anterior nasal (AN) swab samples. The study evaluated the investigational test's performance in symptomatic individuals (those suspected of COVID-19). A total of 412 symptomatic subjects were enrolled and each were currently experiencing symptoms associated with COVID-19, **within 5 days of symptom onset**. Each enrolled subject either self-collected one sample from their anterior nasal passages (from both nostrils), or had one sample collected from him/her by another individual. Each subject then had a mid-turbinate sample collected from him/her by one of the study personnel. Test results from the MaximBio ClearDetect™ COVID-19 Antigen Home Test (candidate test) were compared to highly sensitive molecular FDA EUA Authorized SARS-CoV-2 assays to determine test performance. As shown, the positive percent agreement (PPA) is 86.9% and the negative percent agreement (NPA) is 98.9% with the 95% confidence interval bounds of 76.2% to 93.2% for the PPA and 97.1% to 99.6% for the NPA, respectively.

MaximBio ClearDetect™ COVID-19 Antigen Home Test	RT-PCR Positives	RT-PCR Negatives	Total
Positives	53	4	57
Negatives	8	347	355
Total	**61**	**351**	**412**
Positive Percent Agreement (PPA) = (53/61) x 100% = 86.9% (95% CI: 76.2-93.2%)			
Negative Percent Agreement (NPA) = (347/351) x 100% = 98.9% (95% CI: 97.1-99.6%)			

Subject Age	Female	Male	Positives	% Positivity Rate
<14 years of age	9	14	5	21.7%
14-24 years of age	25	16	10	24.4%
>24-64 years of age	195	110	41	13.4%
≥65 years of age	28	15	5	11.6%
Total	**257**	**155**	**61**	**14.8%**

Days of COVID-19 Symptoms	Number of Specimens Tested	Confirmed Positives	RT-PCR Positives	PPA
Day 0-1	108	10	12	83.3%
Day 2	149	17	18	94.4%
Day 3	91	8	10	80.0%
Day 4	47	16	19	84.2%
Day 5	17	2	2	100.0%
Total	**412**	**53**	**61**	**86.9%**

TECHNICAL SUPPORT

For questions, or to report a problem, please call Technical Support at (301) 251-0800 (Available hours: Mon. to Fri.: 9 a.m. – 4 p.m. EST) or tech@maximbio.com.

SYMBOLS AND ABBREVIATIONS

The following symbols may appear in MaximBio ClearDetect™ COVID-19 Antigen Home Test product labeling.

REF	Part Number	IVD	For In-Vitro Diagnostic Use Only
LOT	Lot Number (Batch Code)	Σ	Tests Per Kit
	Use by (Expiration Date)		Consult Instructions for Use
	Temperature Limitations (Storage Temperature)		Manufacturer
2	One Time Use (Single Use Only)		Date of Manufacture