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 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.

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

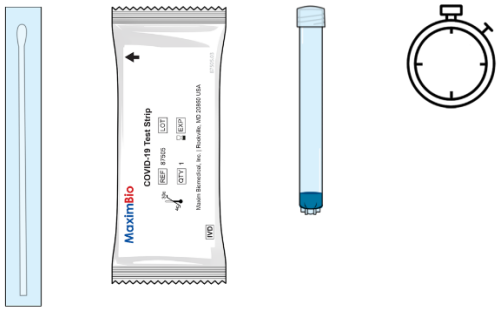
- Timer

5. QUALITY CONTROL

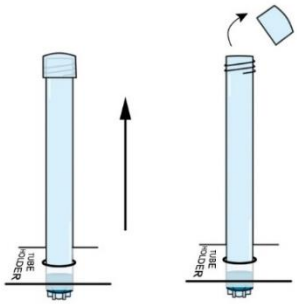
Each MaximBio ClearDetect™ COVID-19 Antigen Home Test has a built-in internal procedural control. The reddish pink line appearing at the “C” position is an internal procedural control. This procedural Control Line indicates that sufficient flow has occurred, and the functional integrity of the test device 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

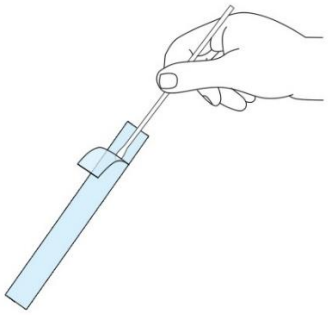
1. Check the test expiration printed on the kit box. Wash or sanitize your hands. Make sure they are dry before starting. Ensure space is clean prior to testing. Required testing components: 1 Swab, 1 Test Strip in Pouch, 1 Tube of Sample Buffer, Timer (not included).



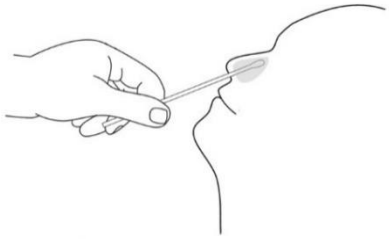
2. Place the tube upright in the tube holder/stand. Remove cap – DO NOT discard. Save the cap for use in Step 9.



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

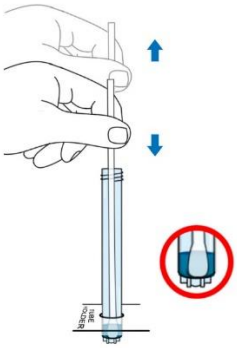


4. Gently insert the swab tip into one nostril about ½ to ¾ of an inch. Do not insert the swab any farther if you feel any resistance. Using medium pressure, rub the swab tip against the inside wall of the one nostril. Make at least 5 large circles (about 15 seconds). Do not just spin the swab.

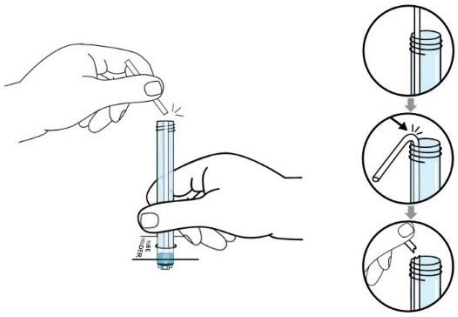


5. Using the same swab, repeat Step 4 in the other nostril.
Note: Both nostrils must be swabbed to ensure accurate results.
Note: If you are swabbing others, please wear a face mask. With children, you may not need to insert the swab as far into the nostril. For very young children, you may need another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

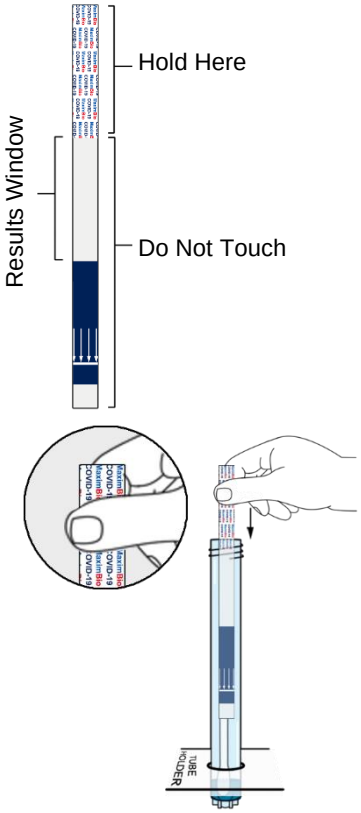
6. Completely submerge swab tip into the liquid inside the tube and set a 30 second timer. Repeatedly plunge for 30 seconds (approximately 30-60 plunges) or more. Mix by firmly pressing the swab tip to the bottom of the tube with each down motion. *Note: this step is very important, do not mix for less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



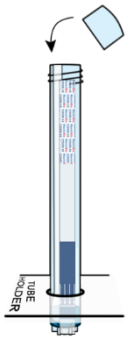
7. Make sure the swab tip is in the liquid inside of the tube. While using one hand to securely hold the tube down, use the other hand to carefully break the swab handle against the side of the tube. Discard the swab handle and leave the broken swab tip in the tube.



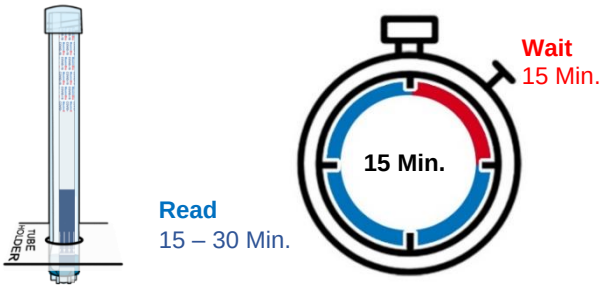
8. Open the test strip pouch carefully at tear notch and hold the test strip as shown. Hold the “MaximBio COVID-19” side of the test strip and carefully place it into the tube, facing outwards, so the results window is clearly visible. ***Note: If test strip is inserted upside down, discard all test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



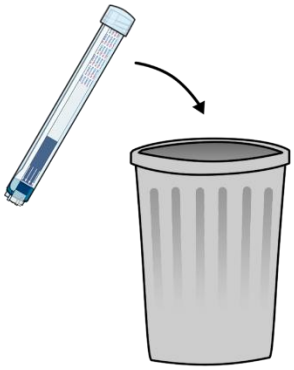
9. Keep tube UPRIGHT during entire test. Make sure the test strip touches the bottom of the tube. While keeping the tube upright, secure the cap on the tube.



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.

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

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

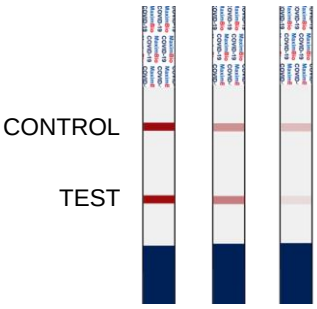
Results should be considered in the context of an individual's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19.

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.

COVID-19 Positive (+)
Find the result area and look carefully for two red/pink lines.
Positive Result: If the Control (C) line and the Test (T) line are visible, the test is positive. Any faint visible red/pink test (T) line with the control line (C) should be read as positive.

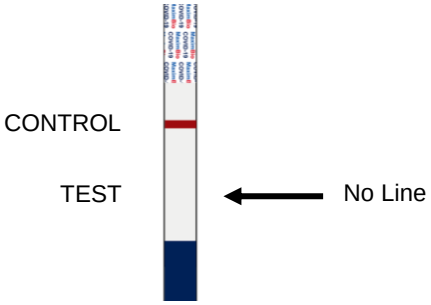
Repeat testing does not need to be performed if patients have a positive result at any time.

A positive test result means that the virus that causes COVID-19 was detected in the sample, and it is very likely the individual has COVID-19 and is contagious. Please contact the patient's doctor/primary care physician (if applicable) and the local health authority immediately and instruct your patient to 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).



Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Individuals who test positive with the [Test Name] should self-isolate and seek follow up care with their physician or healthcare provider as additional confirmatory testing with a molecular test for positive results may also be necessary, if there is a low likelihood of COVID- 19, such as in individuals without known exposures to COVID-19 or residing in communities with low prevalence of infection.

COVID-19 Negative (-)
Find the result area and look carefully for a single red/pink line.
Negative Result: If the Control (C) line is visible, but the Test (T) line is not visible, the test is negative.



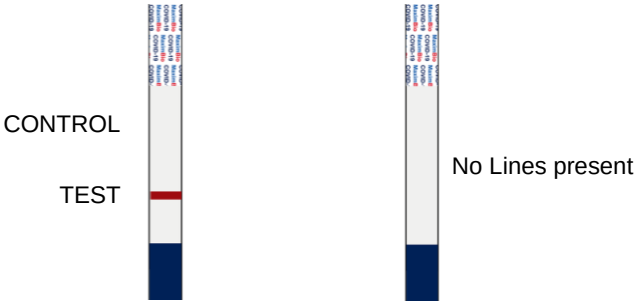
To increase the chance that the negative result for COVID-19 is accurate, you should:

- **Test again in 48 hours if the individual has symptoms on the first day of testing.**
- **Test 2 more times at least 48 hours apart if the individual does not have symptoms on the first day of testing.**

A negative test result indicates that the virus that causes COVID-19 was not detected in the sample. A negative result does not rule out COVID-19. There is a higher chance of false negative results with antigen tests compared to laboratory-based tests such as PCR tests. If the test is negative but COVID-19-like symptoms, e.g., fever, cough, and/or shortness of breath continue, follow up testing for SARS-CoV-2 with a molecular test or testing for other respiratory disease should be considered. If applicable, seek follow up care with the primary health care provider.

All negative results should be treated as presumptive and confirmation with a molecular assay 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. 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.

Invalid
If the control (C) line is not visible, the test is invalid. Re-test with a new swab and new test device.
If results are invalid again after retesting, please call technical support.



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

9. WARNINGS, PRECAUTIONS, AND SAFETY INFORMATION

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

2. 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.
3. **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.**
4. 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.
5. 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.
6. Do not use on anyone under 2 years of age.
7. Wear a safety mask or other face-covering when collecting a specimen from a child or another individual.
8. Do not use if any of the test kit contents or packaging is damaged.
9. Test components are single-use. Do not re-use.
10. Do not use kit past its expiration date.
11. Do not touch the swab tip.
12. Once opened, the test strip should be used within 5 minutes.
13. **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.**
14. **Keep testing kit and kit components away from children and pets before and after use. Avoid contact with your skin, eyes, or mouth. Do not ingest any kit components. The reagent solution contains harmful chemicals (see table below). If the solution contacts your skin, eyes, or mouth, flush with large amounts of water. If irritation persists, seek medical advice: https://www.poisonhelp.org or 1-800-222-1222.**
15. MaximBio ClearDetect™ COVID-19 Antigen Home Test should be performed at ambient temperature (i.e., 15-30°C).

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%
Tris-HCl	H320, Causes eye irritation H316, Causes mild skin irritation	0.314%
Sodium chloride	H320, Causes eye irritation	1.75%
NP-40	H320, Causes eye irritation H316, Causes mild skin irritation	0.6%

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

10. LIMITATIONS

- 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.
- 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.
- This device is only used for testing direct human anterior nasal swab specimens. Viral transport media (VTM) should not be used with this test.
- All COVID-19 antigen test negative results are presumptive and confirmation with a molecular assay may be necessary.
- If the patient continues to have symptoms of COVID-19, and both the patient's first and second tests are negative, the patient may not have COVID-19, however additional follow-up may be needed.
- If the test is positive, then proteins from the virus that causes COVID-19 have been found in the sample and the individual likely has 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.
- 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.

11. PERFORMANCE CHARACTERISTICS

A prospective clinical study was conducted between January 2021 and May 2022 as a component of the Rapid Acceleration of Diagnostics (RADx) initiative from the National Institutes of Health (NIH). A total of 7,361 individuals were enrolled via a decentralized clinical study design, with a broad geographical representation of the United States. Per inclusion criteria, all individuals were asymptomatic upon enrollment in the study and at least 14 days prior to it and did not have a SARS-CoV-2 infection in the three months prior to enrollment. Participants were assigned to one of three EUA authorized SARSCoV-2 OTC rapid antigen tests to conduct serial testing (every 48 hours) for 15 days. If an antigen test was positive, the serial-antigen testing result is considered positive.

At each rapid antigen testing time point, study subjects also collected a nasal swab for comparator testing using a home collection kit (using a 15-minute normalization window between swabs). SARS-CoV-2 infection status was determined by a composite comparator method on the day of the first antigen test, using at least two highly sensitive EUA RT-PCRs. If results of the first two molecular test were discordant a third highly sensitive EUA RT-PCR test was performed, and the final test result was based upon the majority rule.

Study participants reported symptom status throughout the study using the MyDataHelps app. Two-day serial antigen testing is defined as performing two antigen tests 36 – 48 hours apart. Three-day serial antigen testing is defined as performing three antigen tests over five days with at least 48 hours between each test.

Out of the 7,361 participants enrolled in the study, 5,609 were eligible for analysis. Among eligible participants, 154 tested positive for SARS-CoV-2 infection based on RTPCR, of which 97 (62%) were asymptomatic on the first day of their infection, whereas 57 (39%) reported symptoms on the first day of infection. Pre-symptomatic subjects were included in the positive percent agreement (PPA) of asymptomatic individuals, if they were asymptomatic on the first day of antigen testing, regardless of whether they developed symptoms at any time after the first day of testing. Performance of the antigen test with serial testing in individuals is described in the table below.

Table: Data establishing PPA of COVID-19 antigen serial testing compared to the molecular comparator single day testing throughout the course of infection with serial testing. Data is from all antigen tests in study combined.

DAYS AFTER FIRST PCR POSITIVE TEST RESULT	ASYMPTOMATIC ON FIRST DAY OF TESTING			SYMPTOMATIC ON FIRST DAY OF TESTING		
	Ag Positive / PCR Positive (Antigen Test Performance % PPA)					
	1 Test	2 Tests	3 Tests	1 Test	2 Tests	3 Tests
0	9/97 (9.3%)	35/89 (39.3%)	44/78 (56.4%)	34/57 (59.6%)	47/51 (92.2%)	44/47 (93.6%)
2	17/34 (50.0%)	23/34 (67.6%)	25/32 (78.1%)	58/62 (93.5%)	59/60 (98.3%)	43/43 (100%)
4	16/21 (76.2%)	15/20 (75.0%)	13/15 (86.7%)	55/58 (94.8%)	53/54 (98.1%)	39/40 (97.5%)
6	20/28 (71.4%)	21/27 (77.8%)	16/18 (88.9%)	27/34 (79.4%)	26/33 (78.8%)	22/27 (81.5%)
8	13/23 (56.5%)	13/22 (59.1%)	4/11 (36.4%)	12/17 (70.6%)	12/17 (70.6%)	7/11 (63.6%)
10	5/9 (55.6%)	5/8 (62.5%)		4/9 (44.4%)	3/7 (42.9%)	

1 Test = one (1) test performed on the noted days after first PCR positive test result. Day 0 is the first day of documented infection with SARS-CoV-2.
2 Tests = two (2) tests performed an average of 48 hours apart. The first test performed on the indicated day and the second test performed 48 hours later.
3 Tests = three (3) tests performance an average of 48 hours apart. The first test performed on the indicated day, the second test performed 48 hours later, and a final test performed 48 hours after the second test.

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. 50µL of solution was spiked to each swab then processed per the IFU. Based upon the testing procedure for this study the LoD of 750 $TCID_{50}$/mL equates to 37.5 $TCID_{50}$/swab.

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
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 cleardetect@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