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GENABIO

Quick Reference Instructions

GenaCheck® COVID-19 Rapid Self-Test

A rapid test for the detection of SARS-CoV-2 antigens in anterior nasal swab specimens.
For *in vitro* diagnostic use only
Carefully read the instructions before performing the test. Failure to follow the instructions may result in inaccurate test results. A full IFU with performance data can be found at https://www.genabio.com/COVID-19

Warnings and Precautions

Read all instructions carefully before performing the test. Failure to follow directions may produce inaccurate test results.
· Do not use the test if you have had symptoms for more than 5 days or no symptoms at all.
· This test is for use in individuals with symptoms of respiratory infection that started within the last 5 days and serial (repeat) testing should be performed for initial negative results (see Interpretation of Results section). You may need to purchase additional tests to perform this serial (repeat) testing.
- This test is read visually. Individuals with impaired vision should ensure help in interpretation of their test results.
- Ensure that there is sufficient lighting for testing and interpretation.
- Do not use this test kit beyond its expiration date.
- Do not use if any of the test kit contents or packaging is damaged or open.
- Test components are single use. Do not re-use.
- Do not use the test on children under 2 years of age.
- Wear a face mask or other face covering when collecting specimen from a child or another individual.
- Use of personal protection materials such as gloves is recommended. Change gloves between tests.
- The test should be performed immediately after removing from the pouch. Do not use the test cassette after it has been opened for one hour.
- Do not use any nasal sprays, gels or creams at least 30 minutes before you collect a nasal sample.
- Do not eat, drink, or smoke in the area where the specimens and kit contents are handled.
- In the event of spillage, ensure the spill is cleaned thoroughly using a suitable disinfectant.
- Do not ingest any kit components.
- Wash hands thoroughly before and after handling.
- Ensure that hands are completely dry if you used hand sanitizer prior to testing.
- Dispose of kit components and patient samples in household trash.

Keep the testing kit and kit components away from children and pets before and after use. The chemicals in the reagent solution may be hazardous to the 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 call: 1-800-222-1222.

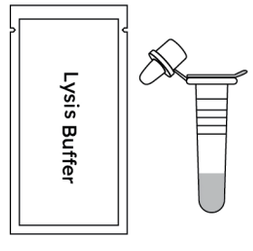
Chemical Name	GHS Code		Concentrations w/w%
Triton X-100	H302	Harmful if swallowed	0.10%
	H315	Causes skin irritation	
	H318	Causes serious eye damage	
NP40	H302	Harmful if swallowed	1%
	H315	Causes skin irritation	
	H318	Causes serious eye damage	
	H319	Causes serious eye irritation	

Test Procedure

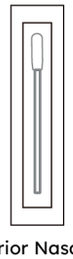
1 Prepare Materials

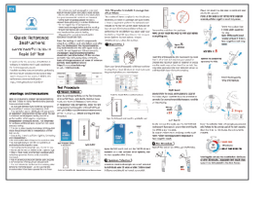
Open the package and take out the Test Cassette within a Foil Pouch, Lysis Buffer, Anterior Nasal Swab, and the Quick Reference Instructions.
If the product was refrigerated, allow the test components (Test Cassette within a Foil Pouch and Lysis Buffer) to equilibrate to room temperature [59-86°F(15-30°C)] before starting the Test Procedure.

Test Cassette within a Foil Pouch



Lysis Buffer


Anterior Nasal Swab

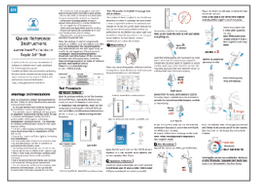

Quick Reference Instructions

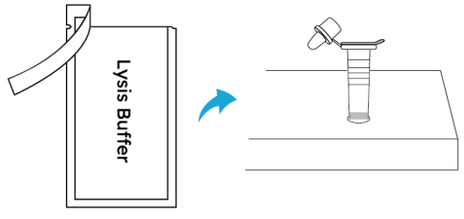
Note: This product is available in package sizes of 2, 4, 20 tests.

The number of items supplied in the kit will vary depending on which kit package size is purchased. A timer is required to perform the test and is not included in the test kit. Do not begin if you do not have at least 25 minutes available to focus on performing the test. Before you begin, wash your hands for at least 20 seconds and then dry your hands. Perform the test indoors, at room temperature on a clean, flat surface.

2 Preparation

Clean your hands thoroughly with hand sanitizer or soap for at least 20 seconds and make sure they are dry before you start the test.


Read the Quick Reference Instructions

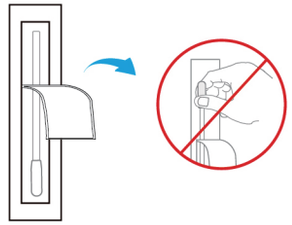


Open the foil pouch and take the Lysis Buffer out

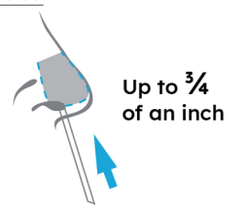
Open the foil pouch and put the COVID-19 test cassette on a flat surface. Once opened, use the test cassette within 1 hour.

3 Specimen Collection

An anterior nasal swab sample can be self-collected by individuals aged 14 years or older. Children aged 2-13 years old should be tested by an adult.



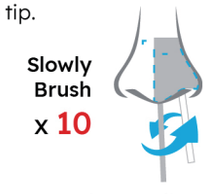
Remove the swab from the package.
Note: Do not touch the swab tip with your hands or anything else.



Insert the entire swab tip into your nostril (no more than ¾ of an inch (1.9 cm) into your nose). For children the maximum depth of insertion of swabs into the nostril may be less than ¾ of an inch. You may need additional help from the other person to hold the child's head for swab sampling.

Right Nostril

Slowly rotate the swab, gently pressing against the inside of your nostril 10 times for a total of 15 seconds. Get as much nasal discharge as possible on the swab tip.

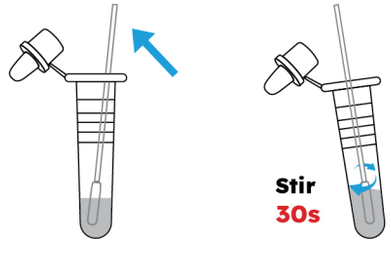


Left Nostril

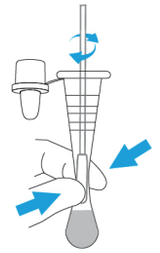
Gently remove the swab, use the SAME SWAB and repeat the steps in your other nostril with the SAME end of the swab.
Be sure to collect nasal drainage on the swab.
Note: Failure to swab properly may cause a false negative result.

4 Test Procedure

Tear off the seal on top of the Lysis Buffer tube.

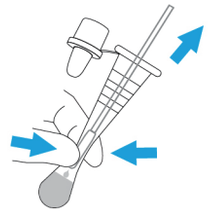


Place the swab into the tube immediately and stir for 30 seconds.
Note: If the swab is not stirred for at least 30 seconds, a false negative result may occur.

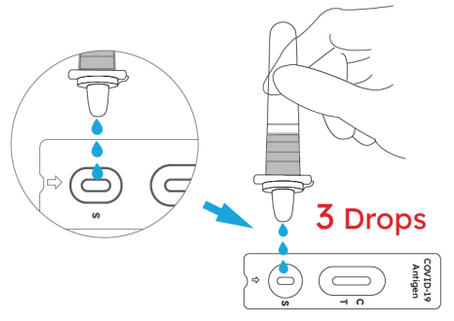


Rotate the swab at least 5 times while squeezing the tube.
Note: If the swab is not rotated at least 5 times, a false negative result may occur.

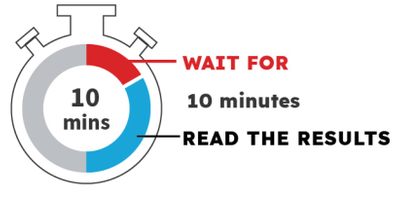
Remove the swab while squeezing the tube.



Attach the dropper tip firmly onto the tube.



Invert the collection tube with sample, squeeze and add **3 drops** to the sample well of the test cassette. Start the timer for 10 minutes. Do not move the cassette.



Warning: Do not read the result before 10 minutes or after 30 minutes. Inaccurate test results may occur if not interpreted in this time frame.

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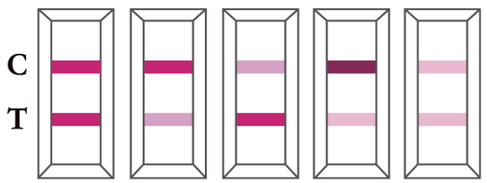
5 Result Interpretation

Positive



The test is Positive if:
There are two colored lines.
There are two colored lines, even if the color of the line next to the T is Faint. Look Closely!
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.

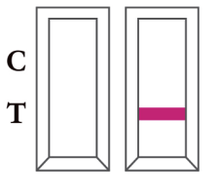
Note: Any faint visible pink color test (T) line should be interpreted as positive, when the Control (C) line is also present. The Test (T) line may vary in shade and intensity (light or dark, weak or strong) depending on the concentration of antigen present in the sample. The intensity of the Control (C) line should not be compared to that of the Test (T) line for interpretation of the test result.

Negative

If the Control (C) line is visible, but the Test (T) line is not visible, the test is negative.

A negative test result indicates that the virus that causes COVID-19 was not detected in your sample. Repeat testing is needed to improve test accuracy. If your first test result is negative, you must repeat testing (serial testing) with another test between 24 and 48 hours later, however negative results do not rule out infection.

Invalid



If no line appears in the Control (C) area, the test results are invalid regardless of the presence or absence of a line in the Test (T) area. An invalid result means the test was not able to tell if you have COVID-19 or not. If the test is invalid, re-test with a new swab and new test device.

For detailed instructions, please visit:
https://www.genabio.com/COVID-19

Intended Use

The GenaCheck COVID-19 Rapid Self-Test is a visually read lateral flow immunoassay test intended for the rapid, qualitative detection of SARS-CoV-2 virus nucleocapsid protein antigen directly in anterior nasal swab specimens from individuals with signs and symptoms of COVID-19.

This test is for non-prescription home use by individuals aged 14 years or older testing themselves, or adults testing individuals aged 2 years or older.

All negative results are presumptive. Symptomatic individuals with an initial negative test result must be re-tested once between 48 and 72 hours after the first test using either an antigen test or a molecular test for SARS-CoV-2. Negative results do not preclude SARS-CoV-2 infections or other pathogens and should not be used as the sole basis for treatment.

Positive results do not rule out co-infection with other respiratory pathogens.

This test is not a substitute for visits to a healthcare provider or appropriate follow-up and should not be used to determine any treatments without provider supervision. Individuals who test negative and experience continued or worsening COVID-19 like symptoms, such as fever, cough and/or shortness of breath, should seek follow up care from their healthcare provider.

The performance characteristics for SARS-CoV-2 were established from March 2024 to October 2024 when SARS-CoV-2 Omicron was dominant. Test accuracy may change as new SARS-CoV-2 viruses emerge. Additional testing with a lab-based molecular test (e.g., PCR) should be considered in situations where a new virus or variant is suspect.

Materials

Materials Provided

- Test Cassette within a Foil Pouch
- Lysis Buffer
- Anterior Nasal Swab
- Quick Reference Instructions

Materials Required but Not Provided

- Timer, Clock or Watch

Storage and Stability

Store the GenaCheck® COVID-19 Rapid Self-Test between [36-86°F(2-30°C)]. Ensure that 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 cassette must remain in the sealed pouch until use.

Limitations

- The clinical performance of this test was established based on the evaluation of a limited number of clinical specimens collected between March 2024 and October 2024 when the Omicron strain was most prevalent. Test accuracy may change as new SARS-CoV-2 viruses emerge. Additional testing with a lab-based molecular test (e.g., PCR) should be considered in situations where a new virus or variant is suspected..
- 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.
- All 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.
- A false-negative test result may occur if the level of antigen in a sample is below the detection limit of the test.
- Excessive non-alcohol hand sanitizer lotion may interfere with test result if it contaminates the specimen.
- This test is read visually. Because test lines can be very faint, users with conditions affecting their vision- such as far-sightedness, glaucoma, or color blindness-are encouraged to seek assistance to interpret results accurately (e.g., reading glasses, additional light source, or another person). This test has not been validated for use by those with color-impaired vision.
- Persons with risk factors for severe disease from respiratory pathogens (e.g., chronic lung or heart disease, compromised immune system, diabetes or other conditions listed by CDC) should consult and follow-up with a healthcare provider, who will advise if additional testing or treatment are 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 additional follow-up may be needed.

Frequently Asked Questions

Q: WHAT ARE THE KNOWN AND POTENTIAL RISKS AND BENEFITS OF THE TEST?
A: Potential risks include:
-Possible discomfort during sample collection.
-Possible incorrect test result(see Warnings and Result Interpretation sections for more information).

Potential benefits include:
-The results, along with other information, can help you and your healthcare provider make informed recommendations about your care.
-The results of this test may help limit the potential spread of COVID-19 to your family and others in your community.

Q: WHAT IS THE DIFFERENCE BETWEEN AN ANTIGEN AND MOLECULAR TEST?
A: There are different kinds of tests for the SARS-CoV-2 virus that causes COVID-19. Molecular tests detect genetic material from the virus. Antigen tests, like the GenaCheck COVID-19 Rapid Self-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 false negative result when you have COVID-19 than a molecular test would.

Q: HOW ACCURATE IS THIS TEST?
A: Clinical studies have shown that antigen tests more accurately determine whether you are infected with the virus that causesCOVID-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: https://www.genabio.com/COVID-19

Q: WHAT IF I HAVE A POSITIVE TEST RESULT?
A: 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.

Q: WHAT IF I HAVE A NEGATIVE TEST RESULT?
A: 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 48hours since antigen tests are not as sensitive as molecular tests. If you have a negative result, it does not rule out SARS-CoV-2 infection. or infection with other pathogens; 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.

Q: WHAT DOES AN INVALID TEST RESULT MEAN?
A: 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.

Q: DO I HAVE TO REPORT MY RESULTS? (OPTIONAL)
A: Report your test result(s) at MakeMyTestCount.org - this voluntary and anonymous reporting helps public health teams understand COVD-19 spread in your area and across the country and informs public health decisions.
Securely report your GenaCheck® COVID-19 Rapid Self-Test result to public health teams by visiting:
https://makemytestcount.org/genabiodiagnostics

Healthcare Providers

Please visit **https://www.genabio.com/COVID-19** to obtain the complete instructions for use.

Index of Symbols

	Do Not Re-use		Consult Quick Reference Instructions
Σ	Test Per Kit	30°86°F 2°30°C	Store At 36-86°F(2-30°C)
LOT	Batch Number	REF	Catalog #
UDI	Unique Device Identifier	IVD	In Vitro Diagnostic Medical Device
	Expiration Date		Keep Away From Sunlight
	Keep Dry		Do Not Use If Package Is Damaged

Assistance

For questions or comments please call Genabio Customer Service at 1-800-614-3365 (9:00 a.m. to 5:00 p.m. EST).

Genabio Diagnostics Inc.
19 Crosby Dr., Ste 220, Bedford MA, 01730, USA
info@genabio.com
Toll-Free: 1-800-614-3365
9:00 a.m. to 5:00 p.m. EST
www.genabio.com

Document No.: RA9-Q02800-00

GenaCheck® COVID-19 Rapid Self-Test Healthcare Provider Instructions for Use

For use with anterior nasal (nares) swab specimens

For *in vitro* diagnostic use only

This document provides you with more information about this test. Please READ this information completely before starting the test.

If you have any questions regarding the use of this product or a test system problem, please contact Genabio Diagnostics Inc. via email: info@genabio.com, or via phone: 1-800-614-3365. Test system problems may also be reported to the FDA through the MedWatch medical products reporting program (phone: 800.FDA.1088; fax: 800.FDA.0178; or go to FDA website at http://www.fda.gov/medwatch).

Intended Use

The GenaCheck COVID-19 Rapid Self-Test is a visually read lateral flow immunoassay test intended for the rapid, qualitative detection of SARS-CoV-2 virus nucleocapsid protein antigen directly in anterior nasal swab specimens from individuals with signs and symptoms of COVID-19.

This test is for non-prescription home use by individuals aged 14 years or older testing themselves, or adults testing individuals aged 2 years or older.

All negative results are presumptive. Symptomatic individuals with an initial negative test result must be re-tested once between 48 and 72 hours after the first test using either an antigen test or a molecular test for SARS-CoV-2. Negative results do not preclude SARS-CoV-2 infections or other pathogens and should not be used as the sole basis for treatment.

Positive results do not rule out co-infection with other respiratory pathogens.

This test is not a substitute for visits to a healthcare provider or appropriate follow-up and should not be used to determine any treatments without provider supervision. Individuals who test negative and experience continued or worsening COVID-19 like symptoms, such as fever, cough and/or shortness of breath, should seek follow up care from their healthcare provider.

The performance characteristics for SARS-CoV-2 were established from March 2024 to October 2024 when SARS-CoV-2 Omicron was dominant. Test accuracy may change as new SARS-CoV-2 viruses emerge. Additional testing with a lab-based molecular test (e.g., PCR) should be considered in situations where a new virus or variant is suspect.

Test Principle

COVID-19 (short for 'Coronavirus Disease 2019') is a disease caused by the coronavirus SARS-CoV-2, first identified in 2019. The incubation period of COVID- 19 is 1 to 14 days, most commonly 3 to 7 days. The main symptom manifestations include fever, fatigue, and dry cough. Nasal congestion, runny nose, sore throat, loss of taste and smell, nausea, myalgia, and diarrhea are also found in some cases.

The GenaCheck® COVID-19 Rapid Self-Test is a rapid, qualitative latex bead based immunochromatography test. The test is designed to detect nucleocapsid protein antigen in self-collected anterior nasal swab specimens from individuals who show symptoms of COVID-19 infection within the first five (5) days of symptom onset. The GenaCheck® COVID-19 Rapid Self-Test is validated for use from direct specimens testing without transport media.

The test cassette contains the following parts: binding pad, test region (T line) and control region (C line). The binding pad of the test cassette is coated with anti-SARS-CoV-2 antibodies which are labeled with latex beads. The test region is coated with monoclonal anti-SARS-CoV-2 antibodies. The control region is coated with goat anti-mouse IgG antibodies. When testing, the anti-SARS-CoV-2 antibodies labeled with latex beads form immunocomplexes with the antigen protein of the virus in the specimen, if present. As a result of chromatography, immuno-complexes move along the membrane and will be captured by the anti-SARS-CoV-2 monoclonal antibodies coated in the test region to form a visible line with red color. The anti-SARS-CoV-2 antibodies or immune complexes continue to move forward and specifically bind to the goat anti-mouse antibody coated in the control region to form a visible line with red color. The results of the test are interpreted at 10 minutes. The red color on the T line and the C line at the same time indicates that the nucleocapsid protein antigen is positive; only the red color on C line appears indicates that the nucleocapsid protein antigen is negative. If no visible signal on C line, the test result is invalid, and this sample needs to be tested again with another test cassette. For additional information, refer to the Interpretation of Results section.

Product Description

The GenaCheck® COVID-19 Rapid Self-Test requires the following elements for operation.

Materials provided in the Test Kit:

Kit Components	Quantity		
	2-Test Kit	4-Test Kit	20-Test Kit
Test Cassette within a Foil Pouch(s)	2/box	4/box	20/box
Anterior Nasal Swab (s)	2/box	4/box	20/box
Lysis Buffer (s)	2/box	4/box	20/box
Quick Reference Instructions	1/box	1/box	1/box

Materials Required but Not Provided:

Timer, Clock or Watch

Quality Control

A procedural internal control is built in the "control line (c)" of the device and is used to ensure that the applied specimen has migrated well into the device. It is coated with anti-mouse IgG and a red colored line should appear after sample was added.

Warnings and Precautions

Read all instructions carefully before performing the test. Failure to follow directions may produce inaccurate test results.

- **Do not use the test if you have had symptoms for more than 5 days or no symptoms at all.**
- **This test is for use in individuals with symptoms of respiratory infection that started within the last 5 days and serial (repeat) testing should be performed for initial negative results (see Interpretation of Results section). You may need to purchase additional tests to perform this serial (repeat) testing.**
- This test is read visually. Individuals with impaired vision should ensure help in interpretation of their test results.
- Ensure that there is sufficient lighting for testing and interpretation.
- Do not use this test kit beyond its expiration date.
- Do not use if any of the test kit contents or packaging is damaged or open.
- Test components are single use. Do not re-use.
- Do not use the test on children under 2 years of age.
- Wear a face mask or other face covering when collecting specimen from a child or another individual.
- Use of personal protection materials such as gloves is recommended.
- The test should be performed immediately after removing from the pouch. Do not use the test cassette after it has been opened for one hour.
- Do not use any nasal sprays, gels or creams at least 30 minutes before you collect a nasal sample.
- Do not eat, drink, or smoke in the area where the specimens and kit contents are handled.
- In the event of spillage, ensure the spill is cleaned thoroughly using a suitable disinfectant.
- Do not ingest any kit components.
- Wash hands thoroughly before and after handling.
- Ensure that hands are completely dry if you used hand sanitizer prior to testing.
- Dispose of kit components and patient samples in household trash.

Keep the testing kit and kit components away from children and pets before and after use. The chemicals in the reagent solution may be hazardous to the 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 call: 1-800-222-1222.

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Limitations

- The clinical performance of this test was established based on the evaluation of a limited number of clinical specimens collected between March 2024 and October 2024 when the Omicron strain was most prevalent. Test accuracy may change as new SARS-CoV-2 viruses emerge. Additional testing with a lab-based molecular test (e.g., PCR) should be considered in situations where a new virus or variant is suspected.
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- 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 additional follow-up may be needed.

Storage and Stability

Store the GenaCheck® COVID-19 Rapid Self-Test between 2-30°C (36-86°F). Ensure that 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 cassette must remain in the sealed pouch until use.

Test Procedure

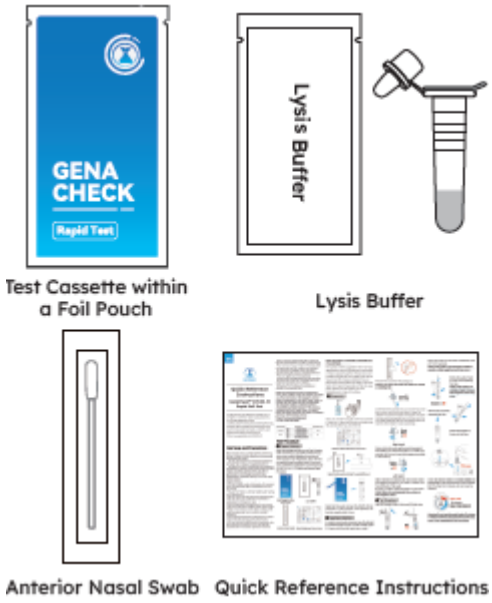
Read instructions carefully before performing a test. Failure to follow directions may produce inaccurate test results.
If stored refrigerated, allow test components (the Test Cassette within a Foil Pouch and Lysis Buffer) to equilibrate to room temperature (15-30°C or 59-86°F) before starting the Test Procedure.

Note:

1. **Please only use the swab provided in the kit for specimen collection.**
2. **Do not touch the tip (specimen collection area) of the swab.**
3. **Collect sample as soon as possible after onset of symptoms.**
4. **Test the sample immediately after collection.**

1. Prepare Materials

- Open the package and take out the Test Cassette within a Foil Pouch, Lysis Buffer, Anterior Nasal Swab, and the Quick Reference Instructions. If the product was refrigerated, allow the test components (Test Cassette within a Foil Pouch and Lysis Buffer) to equilibrate to room temperature [59-86°F(15-30°C)] before starting the Test Procedure.



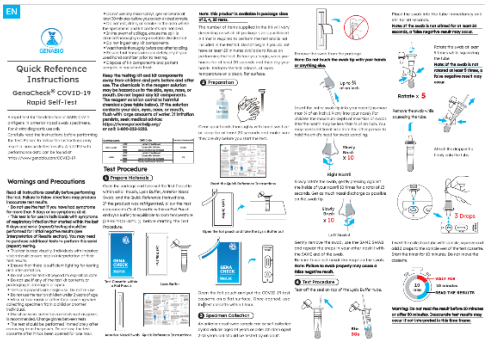
Note: This product is available in package sizes of 2, 4, 20 tests.

- The number of items supplied in the kit will vary depending on which kit package size is purchased. A timer is required to perform the test and is not included in the test kit. Do not begin if you do not have at least 25 minutes available to focus on performing the test. Before you begin, wash your hands for at least

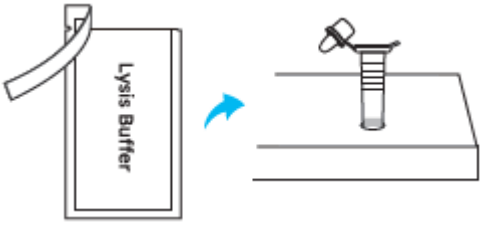
20 seconds and then dry your hands. Perform the test indoors, at room temperature on a clean, flat surface.

2. Preparation

- Clean your hands thoroughly with hand sanitizer or soap for at least 20 seconds and make sure they are dry before you start the test.



- Read the Quick Reference Instructions

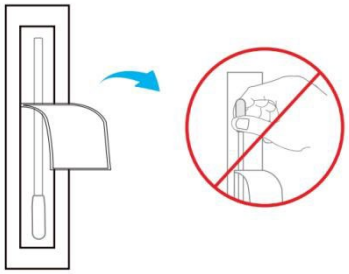


- Open the foil pouch and take the lysis buffer out.

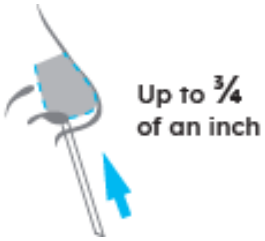
- Open the foil pouch and put the COVID-19 test cassette on a flat surface. Once opened, use the test cassette within 1 hour.

3. Specimen Collection

- An anterior nasal swab sample can be self-collected by individuals aged 14 years or older. Children aged 2-13 years old should be tested by an adult.



- Remove the swab from the package.
- **Note: Do not touch the swab tip with your hands or anything else.**



- Insert the entire swab tip into your nostril (no more than ¾ of an inch (1.9 cm) into your nose).
- For children the maximum depth of insertion of swabs into the nostril may be less than ¾ of an inch. You may need additional help from the other person to hold the child's head for swab sampling.

- Slowly rotate the swab, gently pressing against the inside of your nostril 10 times for a total of 15 seconds. Get as much nasal discharge as possible on the swab tip.

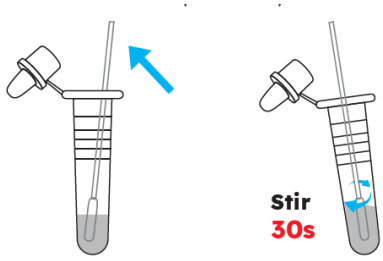
- Gently remove the swab, use the SAME SWAB and repeat the steps in your other nostril with the SAME end of the swab. Be sure to collect nasal drainage on the swab.

Note: Failure to swab properly may cause false negative result.

4. Test Procedure

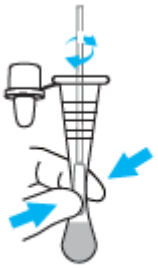
Tear off the seal on top of the collection tube.

-



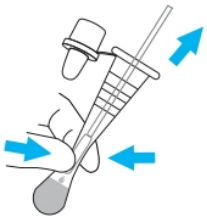
-
-
- Place the swab into the tube immediately and stir for 30 seconds.

Note: If the swab is not stirred for at least 30 seconds, a false negative result may occur.



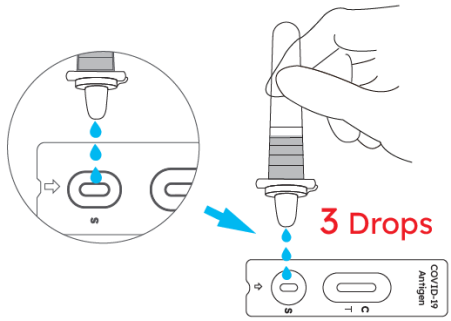
Rotate x 5

- Rotate the swab at least 5 times while squeezing the tube.
- **Note: If the swab is not rotated at least 5 times, a false negative result may occur.**



- Remove the swab while squeezing the tube.

- Attach the dropper tip firmly onto the tube.

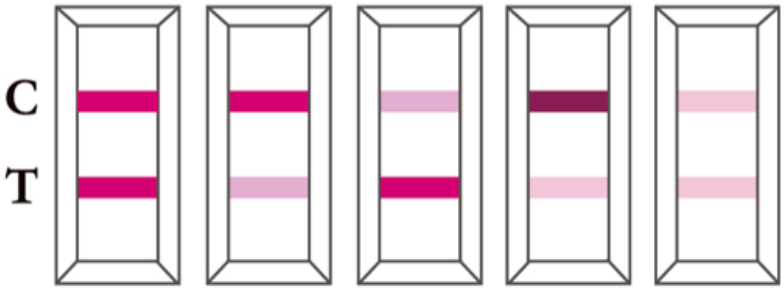


- Invert the collection tube with sample, squeeze and add 3 drops to the sample well of the test cassette.
- Start the timer for 10 minutes. Do not move the cassette.

- **Warning: Do not read the result before 10 minutes or after 30 minutes. Inaccurate test results may occur if not interpreted in this time frame.**

Result Interpretation

Positive

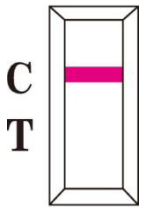


The test is Positive if:
There are two colored lines.
There are two colored lines, even if the color of the line next to the T is Faint. Look Closely!
You do not need to perform repeat testing if you have a positive result at any time.
A positive test result means that the virus that causes COVID-19 was detected in your sample.

Note: Any faint visible pink color test (T) line should be interpreted as positive, when the Control (C) line is also present. The Test (T) line may vary in shade and intensity (light or dark, weak or strong) depending on the concentration of antigen present in the sample. The intensity of the Control (C) line should not be compared to that of the Test (T) line for interpretation of the test result.

Negative

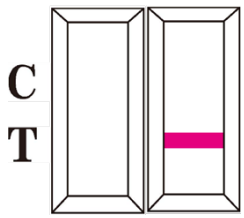
If the Control (C) line is visible, but the Test (T) line is not visible, the test is negative.



A negative test result indicates that the virus that causes COVID-19 was not detected in your sample.

Repeat testing is needed to improve test accuracy. If your first test result is negative, you must repeat testing (serial testing) with another test between 24 and 48 hours later, however negative results do not rule out infection.

Invalid



If no line appears in the Control (C) area, the test results are invalid regardless of the presence or absence of a line in the Test (T) area. An invalid result means the test was not able to tell if you have COVID-19 or not. If the test is invalid, re-test with a new swab and new test device.

Reporting Your Results

Securely report your GenaCheck® Rapid Self-Test result at MakeMyTestCount.org by visiting: https://makemytestcount.org/genabiodiagnostics – 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.

Clinical Performance

Clinical Performance Study

The Clinical Performance Study was conducted from March 2024 to October 2024 as part of the clinical evaluation of the test device to demonstrate the performance characteristics of the GenaCheck® COVID-19 Rapid Self-Test to detect SARS-CoV-2 viral nucleoprotein antigen when used by lay users. The predominantly circulating variant was Omicron during the study period. This was a multi-center, prospective study performed at nine clinical sites in the U.S. One swab was first collected by study staff and used for comparator testing at a central lab with Cepheid Xpert Xpress Sars-CoV-2/Flu/RSV PCR assay. The other swab was collected and tested subsequently with the GenaCheck® COVID-19 Rapid Self-Test by a lay user, either the subject (if aged 14 or older) or the parent/guardian of the subject (between 2-13 years old) in a simulated home-use environment. The GenaCheck® COVID-19 Rapid Self-Test results were compared to a highly sensitive molecular FDA cleared SARS-CoV-2 assay to determine test performance.

The results from the clinical study demonstrate acceptable performance in a total of 643 evaluable subjects, comprising 120 positives and 523 negatives, with an overall sensitivity as estimated by PPA of 93.3% (112/120) (95% CI: 87.4%-96.6%) and specificity as estimated by NPA of 98.7% (539/546, 95% CI: 97.4%-99.4%). The performance is shown in the following table.

Table 1. Clinical Performance of GenaCheck® COVID-19 Rapid Self-Test

GenaCheck Self-Test	Comparator Method		
	Positive	**Negative**	**Total**
Positive	112	7	119
Negative	8	516	524
Total	120	523	643
Positive Percent Agreement (PPA)	93.3% (112/120) (95% CI: 87.4%-96.6%)		
Negative Percent Agreement (NPA)	98.7% (539/546) (95% CI: 97.3%-99.4%)		

Table 2. Performance Stratified by Days Since Symptom Onset

Days Since Symptom Onset	RT-PCR Positive	GenaCheck Positive	Positive Percentage Agreement
1	4	4	100% (51.0-100%)
2	42	39	92.9% (81.0-97.5%)
3	44	40	90.9% (78.8-96.4%)
4	19	18	94.7% (75.4-99.1%)
5	11	11	100% (74.1-100%)
All specimens	120	112	100% (51.0-100%)

Serial Testing

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 SARS-CoV-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 tests 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 RT-PCR, of which 97 (62%) were asymptomatic on the first day of their infection, whereas 57 (39%) reported symptoms on the first day of infection.

Performance of the antigen test with serial testing in individuals is described in the table below.

Table 3: 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	Symptomatic On First Day of Testing		
	Ag Positive / PCR Positive (Antigen Test Performance % PPA)		
	1 Test	2 Tests	3 Tests
0	34/57 (59.6%)	47/51 (92.2%)	44/47 (93.6%)
2	58/62 (93.5%)	59/60 (98.3%)	43/43 (100%)
4	55/58 (94.8%)	53/54 (98.1%)	39/40 (97.5%)
6	27/34 (79.4%)	26/33 (78.8%)	22/27 (81.5%)
8	12/17 (70.6%)	12/17 (70.6%)	7/11 (63.6%)
10	4/9 (44.4%)	3/7 (42.9%)	

1 Test = one (1) test performed on the noted days after the 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 performed 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.

Usability Study

A total of 120 lay users (46% male, 54% female) participated in the usability study, including 106 who performed Self-Tests, and 14 who tested children aged 2-13 years. All successfully completed testing by receiving either Negative or Positive results. 100% of participants reported acceptable questionnaire responses (very easy, easy, or neutral) regarding their ability to understand and follow the QRI. Additionally, 89 % of participants reported favorable responses (very easy and easy) and 11% reported neutral responses (OK) regarding their ability to understand and follow the Quick Reference Instructions.

Readability Study

69 lay users participated in the readability study and evaluated the mock devices. Out of 276 mock device readings, one negative mock device was interpreted as invalid, and four low-positive mock devices (1.5x LoD) were incorrectly read as negative. All strong positive mock devices (5x LoD) were interpreted correctly. Of the four false-negative reading results for the low-positive mock devices (1.5x LoD), two subjects over 55 years old had vision impairments (one near-sighted and one far-sighted). It is therefore recommended that users with conditions affecting their vision, such as far-sightedness, glaucoma, or color blindness, are encouraged to seek assistance to interpret results accurately (e.g., reading glasses, additional light source, or another person). A related warning statement is included in the labelling.

Performance Characteristics

Analytical Sensitivity: Limit of Detection (LoD)

The Limit of Detection (LoD) of the GenaCheck® COVID-19 Rapid Self-Test was determined using serial dilutions

of the characterized heat-inactivated SARS-CoV-2 (USA-WA1/2020). A preliminary LoD concentration was determined by testing a series of 10-fold dilutions of SARS-CoV-2 virus spiked into negative clinical matrix in triplicates. The lowest 10-fold dilution concentration in which all 3 replicates were positive was deemed as the preliminary LoD (4.57E+03 $TCID_{50}$/mL). Samples at the preliminary LoD and additional series of 3-fold dilutions of it were tested in 20 replicates with 3 lots of test kits to identify the lowest concentration that produces 19 out of 20 positive results. The final LoD of the GenaCheck® COVID-19 Rapid Self-Test was determined to be 1.52E+03 $TCID_{50}$/mL.

Table 4. Preliminary LoD Determination

Concentration ($TCID_{50}$/mL)	Number of Positive Results / Number of Repeat Tests
4.57E+06	3/3
4.57E+05	3/3
4.57E+04	3/3
4.57E+03 (Preliminary LoD)	3/3
4.57E+02	0/3

Table 5. LoD Confirmation

Concentration ($TCID_{50}$/mL)	Concentration ($TCID_{50}$ per swab)	Number of Positive Results / Number of Repeat Tests		
		Lot 1	Lot 2	Lot 3
4.57E+03	2.29E+02	20/20	20/20	20/20
1.52E+03	**7.60E+01**	**20/20**	**20/20**	**20/20**
5.08E+02	2.54E+01	0/20	2/20	0/20

WHO Standard Testing

Analytical sensitivity of the GenaCheck® COVID-19 Rapid Self-Test was also evaluated using the 1st WHO International Standard for SARS-CoV-2 Antigen (NIBSC 21/368). A preliminary LoD with the WHO standard was determined to be 250 IU/mL through testing a series of 2-fold dilutions of the antigen spiked into negative clinical matrix in replicates of three. This preliminary LoD was then confirmed by testing an additional twenty (20) replicates at the concentrations 3-fold above and below the preliminary LoD. The results in Table 5 and Table 6 below confirmed the LoD for the WHO International Standard to be 250 IU/mL .

Table 6. Preliminary LoD with WHO Standard

Concentration of the WHO Standard (IU/mL)	Number of Positive Results / Number of Repeat Tests
20,000	3/3
4,000	3/3
2,000	3/3
1,000	3/3
500	3/3
250	**3/3**

125	0/3
62.5	0/3

Table 7. LoD Confirmation with WHO Standard

Concentration of the WHO Standard (IU/mL)	IU/swab	Number of Positive Results / Number of Repeat Tests
750	37.5	20/20
250	**12.5**	**20/20**
83.3	4.17	0/20

Inclusivity (Analytical Reactivity)

The analytical reactivity of the GenaCheck® COVID-19 Rapid Self-Test was demonstrated in the inclusivity study testing the SARS-CoV-2 variants listed in the table below. Each variant was serial diluted by 3 folds in negative clinical matrix and tested in triplicates. The minimum detectable level of each variant is summarized in the table below where all 3 replicates were detected.

Table 8. Inclusivity Study Results

SARS-CoV-2 Variant	Minimum Detectable Level ($TCID_{50}$/mL)
SARS-CoV-2 Lineage XBB; Omicron Variant	7.35E+03
SARS-CoV-2 Lineage BA.2.3; Omicron Variant	1.44E+02
SARS-CoV-2 Lineage BA.5; Omicron Variant	8.15E+02
SARS-CoV-2 Lineage B.1.1.529; Omicron Variant	4.80E+01
SARS-CoV-2 Lineage B.1.617.2; Delta Variant	1.30E+03
SARS-CoV-2 Lineage B.1.1.7; Alpha Variant	1.18E+04
SARS-CoV-2 Lineage B.1.351; Beta Variant	1.88E+03
SARS-CoV-2 Lineage P.1 Brazil; Gamma variant	1.56E+03
SARS-CoV-2; Hong Kong/VM20001061/2020	5.19E+02
SARS-CoV-2; Italy-INMI1	3.93E+03

Traceability, Stability, Expected Values (Controls, Calibrators, or Methods)

Internal Control

The GenaCheck® COVID-19 Rapid Self-Test has a built-in internal procedural control. A red line should always appear in the control line region (C) indicating that proper volume of the sample has been added and that membrane wicking has occurred.

Real Time Stability (Shelf-Life)

The shelf-life of the GenaCheck® COVID-19 Rapid Self-Test was established by testing the performance of three (3) lots of test kits when stored at 2-8 °C and 30±2 °C with high humidity. Prior to long-term storage, the test kits were stored 7 days at 45 °C, 4 hours at room temperature, 7 days at < -20 °C, and 4 hours at room temperature to mimic worst-case transportation condition. All 3 lots were tested with negative and positive (3xLoD) SARS-CoV-2 samples.

Shipping Stability

One lot of test kits were stored at 60 °C with 85% ±5% relative humidity for 8 days and tested daily with negative and positive (3xLoD) samples in replicate of five (5). In addition, three (3) lots of test kits were put through 3 freeze/thaw cycles (24 hours at -20°C /24 hours at room temperature), then stored at 55 °C and tested at 7, 21, and 35 days. All samples produced expected results for the storage conditions across the time points tested.

Analytical Specificity: Cross Reactivity and Microbial Interference

Cross-reactivity and microbial interference studies of the GenaCheck® COVID-19 Rapid Self-Test were performed for related pathogens, high prevalence disease agents, and normal or pathogenic flora that are reasonably likely to be encountered in a clinical specimen from the nasal cavity. Each organism and virus were tested in three replicates in both the absence (cross reactivity) and presence of inactivated SARS-CoV-2 (isolate USA-WA1/2020) at 3x LoD (microbial interference). All testing samples were prepared in negative clinical matrix, and the samples were tested in a randomized and blinded manner. No cross reactivity or interference was observed for any other organisms and viruses tested at the concentrations as shown in the table below.

Table 9. Cross-reactivity and Microbial Interference Study Results

Pathogens Added	Concentration Tested	Cross-reactivity results (Positive/Tested)	Microbial interference results (Positive/Tested)
Adenovirus Type 1	2.23E+05 $TCID_{50}$/mL	0/3	3/3
Adenovirus Type 2	2.13E+06 $TCID_{50}$/mL	0/3	3/3
Adenovirus Type 7A	1.58E+05 $TCID_{50}$/mL	0/3	3/3
Bordetella pertussis	2.90E+08 CFU/mL	0/3	3/3
Candida albicans	1.21E+07 CFU/mL	0/3	3/3
Chlamydia pneumoniae	4.33E+06 IFU/mL	0/3	3/3
Enterovirus Type 68	2.23E+05 $TCID_{50}$/mL	0/3	3/3
Hemophilus influenzae	9.68E+06 CFU/mL	0/3	3/3
Human coronavirus 229E	1.58E+05 $TCID_{50}$/mL	0/3	3/3
Human coronavirus NL63	8.00E+04 $TCID_{50}$/mL	0/3	3/3
Human coronavirus OC43	7.00E+05 $TCID_{50}$/mL	0/3	3/3
Human Metapneumovirus	1.40E+05 $TCID_{50}$/mL	0/3	3/3
Influenza A H1N1	1.85E+08 $CEID_{50}$/mL	0/3	3/3
Influenza A H3N2	6.50E+06 FFU/mL	0/3	3/3
Influenza B Victoria	1.58E+05 $TCID_{50}$/mL	0/3	3/3
Influenza B Yamagata	1.90E+06 $TCID_{50}$/mL	0/3	3/3
Legionella pneumophila	6.50E+06 CFU/mL	0/3	3/3

MERS-coronavirus	1.40E+05 $TCID_{50}$/mL	0/3	3/3
Mycobacterium tuberculosis avirulent	3.03E+06 CFU/mL	0/3	3/3
Mycoplasma pneumoniae	2.50E+07 CFU/mL	0/3	3/3
Parainfluenza virus 1	2.00E+05 $TCID_{50}$/mL	0/3	3/3
Parainfluenza virus 2	1.40E+05 $TCID_{50}$/mL	0/3	3/3
Parainfluenza virus 3	7.00E+05 $TCID_{50}$/mL	0/3	3/3
Parainfluenza virus 4	2.39E+05 $TCID_{50}$/mL	0/3	3/3
Pooled Nasal Wash	N/A	0/3	3/3
Respiratory syncytial virus Type A	3.50E+05 $TCID_{50}$/mL	0/3	3/3
Respiratory syncytial virus Type B	2.29E+05 $TCID_{50}$/mL	0/3	3/3
Rhinovirus 1A	7.05E+04 $TCID_{50}$/mL	0/3	3/3
Rhinovirus B14	1.31E+05 $TCID_{50}$/mL	0/3	3/3
SARS-CoV-1	1.25E+05 PFU/mL	0/3	3/3
Staphylococcus aureus	2.60E+08 CFU/mL	0/3	3/3
Staphylococcus epidermidis	9.00E+07 CFU/mL	0/3	3/3
Streptococcus pneumoniae	1.81E+07 CFU/mL	0/3	3/3
Streptococcus pyogenes	7.50E+07 CFU/mL	0/3	3/3
HKU1 clinical sample 1	Ct value: 31.8	0/3	3/3
HKU1 clinical sample 2	Ct value: 27.4	0/3	3/3
HKU1 clinical sample 3	Ct value: 23.1	0/3	3/3

Interfering Substances

Interference from endogenous and exogenous substances was evaluated by testing GenaCheck® COVID-19 Rapid Self-Test with a panel of substances that may be present in an upper respiratory tract specimen and could potentially interfere with detection of SARS-CoV-2 antigen. The positive (3x LoD) and negative samples were tested with the addition of potentially interfering substances and tested in three replicates. All samples produced expected results demonstrating that the potentially interfering substances listed in the table below do not affect the performance of the GenaCheck® COVID-19 Rapid Self-Test at the concentrations listed in the table below.

Table 10. Interfering Substances Study Results

Interfering Substances Tested	Test Concentration	SARS-CoV-2 Negative Sample (Positive/Tested)	SARS-CoV-2 Positive Sample (Positive/Tested)
Throat Lozenges (Benzocaine, Menthol)	3 mg/mL	0/3	3/3
Sore Throat Spray (Phenol)	5% v/v	0/3	3/3
Mucin (Purified mucin protein)	2.5 mg/mL	0/3	3/3
Whole Blood (Human)	2.5% v/v	0/3	3/3
Leukocytes	2×10^6 cells/mL	0/3	3/3
Throat Spray (Zinc)	15% v/v	0/3	3/3

Nasal Drops (Phenylephrine)	15% v/v	0/3	3/3
Nasal Spray (Cromolyn)	15% v/v	0/3	3/3
Nasal Spray (Oxymetazoline)	15% v/v	0/3	3/3
Nasal Spray (Saline)	15% v/v	0/3	3/3
Nasal corticosteroids (Beclomethasone)	15% v/v	0/3	3/3
Nasal corticosteroids (Dexamethasone)	15% v/v	0/3	3/3
Nasal corticosteroids (Flunisolide)	15% v/v	0/3	3/3
Nasal corticosteroids (Triamcinolone)	15% v/v	0/3	3/3
Nasal corticosteroids (Budesonide)	15% v/v	0/3	3/3
Nasal corticosteroids (Mometasone furoate)	15% v/v	0/3	3/3
Nasal corticosteroids (Fluticasone propionate)	15% v/v	0/3	3/3
Nasal Spray (Zicam, Luffa opperculata, Galphimia glauca, Histaminum hydrochloricum)	15% v/v	0/3	3/3
Alkalol	15% v/v	0/3	3/3
Oseltamivir Phosphate (Tamiflu)	5 mg/mL	0/3	3/3
Remdesivir	10 mg/mL	0/3	3/3
Molnupiravir	10 mg/mL	0/3	3/3
Mupirocin	10 mg/mL	0/3	3/3
Nasal gel	5% v/v	0/3	3/3
Body Lotion (Dimethicone)	0.5% w/v	0/3	3/3
Hand Sanitizer (62% Ethyl alcohol)	5% v/v	0/3	3/3
Hand Sanitizer Cream Lotion* (Benzalkonium chloride)	5% w/v	3/3	3/3
Hand Sanitizer (80% Ethyl alcohol)	15% v/v	0/3	3/3
Hand Soap	10% w/v	0/3	3/3
Biotin	3,500 ng/mL	0/3	3/3

* Hand Sanitizer Cream Lotion was found to not interfere with testing at 1.67% w/v, giving negative results in 3 out of 3 replicates tested.

High-dose Hook Effect

No Hook effect was observed when 50 µL of heat-inactivated SARS-CoV-2 virus stock solution (4.57E+6 $TCID_{50}$/mL) was spiked on to the swab for testing.

Multi-lot Precision Studies

Consistent performance of the GenaCheck® COVID-19 Rapid-Test Kit was demonstrated in two multi-lot precision studies.

In the first study, three sample levels (Negative, 1.5× LoD, 3× LoD) were tested by 2 operators over 12 days with 3 lots of kits in duplicates. On each day, 2 runs (at least 4 hours apart) were carried out with two replicates per run, per operator, per kit lot. As shown in the table below, all samples produced consistent results across all lots, operators, and days.

Table 11: Initial Lot to Lot Precision Study Results

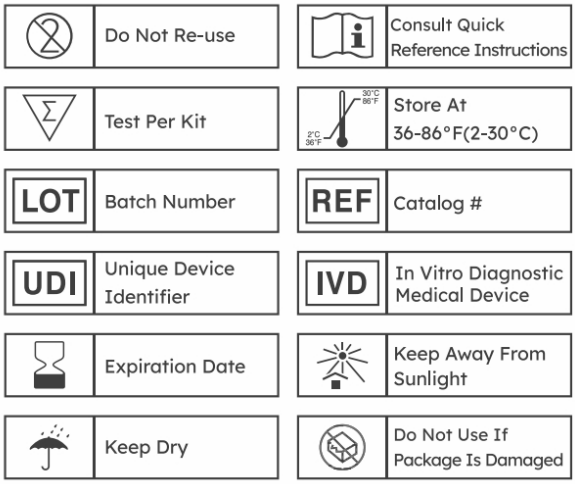
Sample Type	Kit Lot 1	Kit Lot 2	Kit Lot 3	Operator 1	Operator 2	Total Result	% Agreement (95% CI)
Negative	96/96	96/96	96/96	144/144	144/144	288/288	100% (98.68-100%)
Low Positive *1.5×LoD*	96/96	96/96	96/96	144/144	144/144	288/288	100% (98.68-100%)
Moderate Positive *3×LoD*	96/96	96/96	96/96	144/144	144/144	288/288	100% (98.68-100%)

A second study was specifically conducted to further evaluate potential differences between distinct lots, because the initial precision study resulted in 100% agreement across all sources of variation and did not allow a conclusive assessment of lot-to-lot variability of the test. The study was performed using a negative sample and one low positive sample at 0.8 X LoD (i.e., below the concentration tested in the initial study, and near the analyte's C95 concentration) and one positive sample at 3 X LoD. Consistent with the analyte concentration of the low positive sample, the 0.8 X LoD sample resulted in percent agreements less than 95%, with similar results for all lots. The results are summarized in the table below.

Table 12: Supplemental Lot-to-Lot Precision Study Results

Sample Type	Kit Lot 1	Kit Lot 2	Kit Lot 3	Operator 1	Operator 2	Total Result	% Agreement (95% CI)
Negative	48/48	48/48	48/48	72/72	72/72	144/144	100% (97.4-100%)
Low Positive *0.8×LoD*	77/96	80/96	81/96	128/144	110/144	238/288	82.64% (77.8-86.6%)
Moderate Positive *3×LoD*	48/48	48/48	48/48	72/72	72/72	288/288	100% (97.4-100%)

Index of Symbols



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