Genabio COVID-19 Rapid Self-Test Kit

Healthcare Provider Instructions for Use

For use under an Emergency Use Authorization (EUA) Only

For use with anterior nasal (nares) swab specimens

For in vitro diagnostic use

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 if you want to report 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 Genabio COVID-19 Rapid Self-Test Kit 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 years 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 7 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 Genabio COVID-19 Rapid Self-Test Kit 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 Genabio COVID-19 Rapid Self-Test Kit 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 Genabio COVID-19 Rapid Self-Test Kit is intended for non-prescription self-use and/or, as applicable, for an adult lay user testing another person aged 2 years or older in a non-laboratory setting.

The Genabio COVID-19 Rapid Self-Test Kit 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.

Test Principle

COVID-19 (short for 'Coronavirus Disease 2019') is a disease caused by the coronavirus SARS-CoV-2, first identified in Wuhan, China in 2019. Due to its spread around the world, the U.S. Centers for Disease Control and Prevention (CDC) activated its emergency operations in response to the spread of COVID-19 on January 20, 2020. Based on the current epidemiological investigation, 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 found in a few cases.

The Genabio COVID-19 Rapid Self-Test Kit is a rapid, qualitative colloidal gold 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 seven days of symptom onset. The Genabio COVID-19 Rapid Self-Test Kit 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 labelled with colloidal gold marker. 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 labelled with colloidal gold marker form immunocomplexes with the antigen protein of the virus in the specimen. 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 15 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 Genabio COVID-19 Rapid Self-Test Kit requires the following elements for operation.

Materials provided in the Test Kit:

Kit components	Quantity			
	1 test Kit	2 test Kit	5 test Kit	25 test Kit
COVID-19 Test Card(s)	1 ea/box	2 ea/box	5 ea/box	25 ea/box
Nasal Swab(s)	1 ea/box	2 ea/box	5 ea/box	25 ea/box
Tube(s)	1 ea/box	2 ea/box	5 ea/box	25 ea/box
Quick Guide Instruction	1 ea/box	1 ea/box	1 ea/box	1 ea/box

Materials Required but Not Provided

Timer or watch

For Healthcare Provider Instructions for Use, please visit our company website at: https://www.genabio.com

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

- For in vitro diagnostic use.
- In the USA, this product has not been FDA cleared or approved but, has been authorized by FDA under an EUA.
- 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.
- Read all instructions carefully before performing the test. Failure to follow directions may product inaccurate test results.
- This test is intended to aid in a diagnosis of a current SARS-CoV-2 infection. Please consult a healthcare professional to discuss your results and if any additional testing is required.
- **Serial testing should be performed in individuals with negative results at least twice over three**

days (with 48 hours between tests) for symptomatic individuals and three times over five days (with at least 48 hours between tests) for asymptomatic individuals. You may need to purchase additional tests to perform this serial (repeat) testing.

- If the individual has had symptoms longer than 7 days, they should consider testing at least three times over five days with at least 48 hours between tests.
- Proper specimen collection and handling are essential for accurate results.
- Keep the test kit and materials out of reach of children and pets before and after use.
- Use of personal protection materials such as gloves is recommended. Change gloves between tests.
- Wear a safety mask or other face-covering when collecting a specimen from a child or another individual.
- Use only the components of this test kit. Do not mix components from different kit lots. All kit components are intended for single use. Do not use with multiple specimens. Do not reuse the used Test Card. If a test must be repeated, use new components for the retest.
- Remove any piercings from the nose before starting the test.
- Do not open the Test Card pouch packaging until ready to perform a test. Once opened, the test card should be used with 30 minutes.
- The Genabio COVID-19 Rapid Self-Test Kit should be performed at ambient temperature (i.e., 15-30°C).
- Exposure to humidity may decrease the stability of the test.
- The test should be performed immediately after removing it from the pouch. Do not use the test cassette after it has been opened for one hour.
- Test Cards and sample collection devices are intended for a single use. Do not use more than once. If a test must be repeated, use new components for the retest.
- This is a qualitative test; therefore, quantitative values of SARS-CoV-2 antigen concentration cannot be determined.
- The immune response cannot be evaluated using this test. Other test methods are required for that purpose.
- Test devices that contain patient samples should be handled as though they could transmit disease. Follow universal precautions when handling samples, this kit, and its contents.
- Do not use the test kit past the expiration date printed on the outside of the box.
- An anterior nasal swab sample can be self-collected by an individual age 14 years and older. Children aged 2-13 years should be tested by an adult.
- Do not use on anyone under 2 years of age.
- Do not use if any of the test kit components or packaging are damaged or open.
- Do not use nasal sprays for at least 30 minutes before collecting a nasal sample.
- Proper specimen collection and handling are essential for accurate results. Inadequate or inappropriate sample collection may yield false test results.
- Do not touch swab head (specimen collection area) while handling the swab.
- Do not use on anyone who is prone to nosebleeds or who has had facial injuries or head

injuries/surgery in the past six months.

- Do not eat, drink, or smoke in the area where the specimens and kit contents are handled.
- If you suspect the presence of blood on the swab, discard the swab, make sure you are not bleeding, and repeat with a fresh one.
- Ensure the Test Card remains face-up on a flat surface throughout the duration of the test. Improper handling and setup may yield inaccurate results.
- Avoid handling the results window area to minimize contamination.
- The control line may show up within a few minutes of starting the test. It may take up to 15 minutes for a test line to show up.
- Do not read the test result 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.
- After performing the test, read the Test Card results visually in a brightly lit area to ensure accurate interpretation. Ensure that there is sufficient lighting for testing and interpretation.
- A negative test result may occur if the level of antigen in the sample is below the limit of detection of the test.
- This test is intended as an aid in the diagnosis of COVID-19 by detecting viral antigens but should not be used as a sole criterion for the determination of SARS-CoV-2 infection. Other laboratory tests and clinical information (signs and symptoms) should be used and considered for diagnosis.
- In the event of spillage, ensure it is cleaned thoroughly using a suitable disinfectant.
- Do not ingest any kit components.
- Wash hands thoroughly or use hand sanitizer before and after handling.
- Dispose of kit components and patient samples in household trash.
- Keep 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 blow). If the solution contacts your skin, eyes, nose, or mouth, flush with large amounts of water. **If irritation persists, seek medical advice: https://www.poisonhelp.org or 1-800-222-1222.**

Chemical Name	GHS Code for applicable Ingredient	Concentrations W/W %
Triton X-100	Harmful if swallowed(H302) Cause skin irritation(H315) Cause serious eye damage(H318)	0.10%
ProClin®300	Harmful if swallowed (H302) Harmful if inhaled (H332) Causes severe skin burns and eye damage (H314) May cause an allergic skin reaction(H317)	0.05%

If the reagent solution contacts the skin or eye, flush with plenty of water. If irritation persists, seek medical advice. Visit website at https://www.poison.org/contact-us or call toll free number: 1-800-222-1222.
For more information on EUAs please visit:
https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-

framework/emergency-use-authorization
For the most up to date information on COVID-19, please visit:
www.cdc.gov/COVID19

Limitations

- Incorrect test results may occur if a specimen is incorrectly collected or handled.
- There is a higher chance of false negative results with home use 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 you a negative result when you have COVID-19 as compared to a molecular test, especially in samples with low viral load.
- 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.
- This is a qualitative test; therefore, quantitative values of SARS-CoV-2 antigen concentration cannot be determined.
- Failure to follow the test procedure correctly may result in false negative or false positives results and/or invalidate the test result.
- 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.
- Test results should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to determine infection status. Test results should be evaluated in conjunction with other clinical data available to the physician.
- Reading the test results before 15 minutes or after 30 minutes may yield inaccurate test results.
- Negative test results are not indicative of the presence/absence of other viral or bacterial pathogens.
- Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.
- This test and the result from this test do not establish that the user has acquired immunity to COVID-19.
- Positive test results do not differentiate between SARS-CoV and SARS-CoV-2.
- If the differentiation of specific coronaviruses and SARS strains is needed, additional testing, in consultation with state or local public health departments, is required.
- 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.
- Positive test results do not exclude co-infection with other pathogens.
- These test results are shown as lines of color. Because these lines can be very faint, users with

vision impairment - such as far-sightedness or glaucoma - are encouraged to seek assistance to interpret results accurately (e.g., reading glasses, additional light source, or another person with no vision impairment).

- The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between January 2022 and June 2022. The clinical performance has not been established for all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.
- The amount of antigen in a sample may decrease as the duration of illness increases. Specimens collected after seven days are more likely to be negative compared to molecular testing (RT-PCR).
- The performance of the COVID-19 At-Home Test was evaluated using the procedures provided in these Instructions for Use (IFU) only. Modifications to these procedures may alter the performance of the test.
- This device is only used for testing direct human anterior nasal swab specimens. Viral transport media (VTM) should not be used with this test.

Storage and Stability

Store the Genabio COVID-19 Rapid Self-Test Kit 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

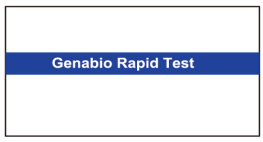
If stored refrigerated, allow test components (COVID-19 Test Pouch and Pre-Filled Tube) to equilibrate to room temperature (15–30°C or 59-86°F) before starting the Test Procedure.

Note:

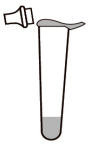
1. Please only use the swab provided in the kit for specimen collection.
2. Do not touch the tip (specimen collection area) of the swab.
3. Collect sample as soon as possible after onset of symptoms.
4. Test the sample immediately after collection.

1. Prepare Materials

- Open the package, take out the COVID-19 Test pouch, the tube pre-filled with the extraction solution and the anterior nasal swab.



COVID-19 Test Pouch



Pre-Filled Tube

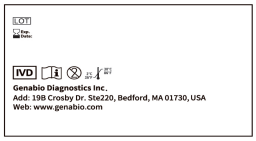
Anterior Nasal Swab

Quick Reference Instructions

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.

- Check the kit's contents and the expiration date.

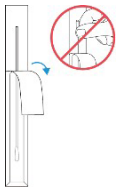


- Open the foil pouch and put the COVID-19 test cassette on a flat surface.
- Proceed immediately to Specimen Collection. Do not use the test cassette after it has been opened for one hour.

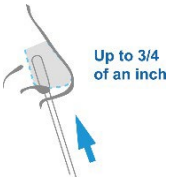
3. Specimen Collection

- An anterior nasal swab sample can be self-collected by adults. Children 2-13 years old should be tested by an adult.
- Remove the swab from the package.

Note: Do not touch the soft end with your hands or anything else.

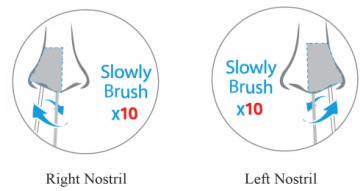


- Insert the entire soft end of the swab into your nostril no more than ¾ of an inch (1.5 cm) into your nose.



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 soft end of the swab.

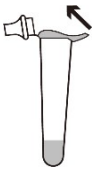


- Gently remove the swab, use the SAME SWAB and repeat steps in your other nostril with the SAME end of the swab.

Note: 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.

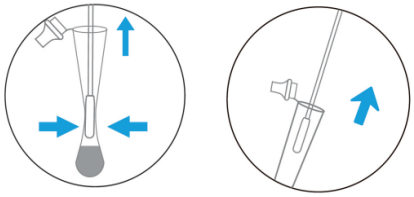


- Place the swab into the collection tube immediately and stir for 30 seconds.

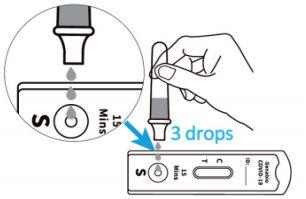
Note: If the swab is not stirred at least 30 seconds, a false negative result may occur.

- Rotate the swab at least 5 times while squeezing the tube.

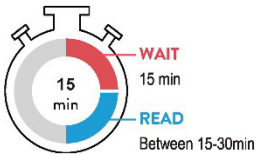
Note: If the swab is not rotated at least 5 times, a false negative result may occur.



- 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 15 minutes. Do not move the cassette.



- After 15 minutes, read results in the result window, labeled as "C" (for Control) and "T" (for Test). It is important to read your results at 15-30 minutes. DO NOT read results after 30 minutes. False negative or false positive results can occur if test results are read outside of the 15-30 minutes reading range.
- See the next section for examples of positive, negative, and invalid test results.

Result Interpretation

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

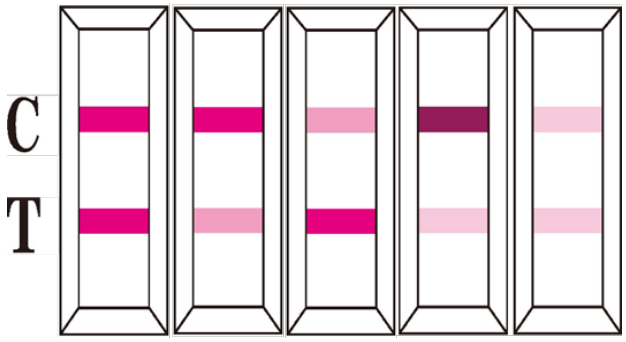
Status on First Day of Testing	First Result Day 1	Second Result Day 3	Third Result Day 5	Interpretation
With Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	N/A	Negative for COVID-19
Without Symptoms	Positive	N/A	N/A	Positive for COVID-19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

Read your results in a well-lit area. Look for lines next to the 'C' (Control) and the 'T' (Test) areas on the Test Device. Use the table below to interpret what you see.

Report your test results to your healthcare provider to receive appropriate medical care.

COVID-19 Positive Result



If the Control (C) line and Test (T) line both appear as pink-colored lines in the show window, the test is positive.

Note: Any faint line in the Test line region (T) should be considered positive. 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 the interpretation of the test result. Any faint visible pink color Test (T) line should be interpreted as positive, when the Control (C) line is also present

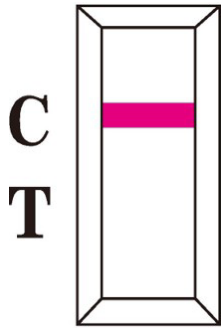
Repeat testing does not need to be performed if patients have a positive result at any time.

A positive test result means that the virus that causes COVID-19 was detected in your sample and it is very

likely the individual has COVID-19 and is contagious. Please contact the patients' doctor/primary care physician 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 Genabio COVID-19 Rapid Self-Test 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 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:

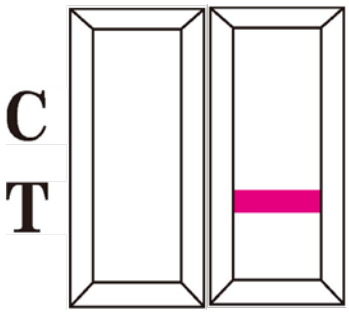
- **Test again in 48 hours if you have symptoms on the first day of testing.**
- **Test 2 more times at least 48 hours apart if you do not have symptoms on the first day of testing.**

A negative test result indicates that the virus that causes COVID-19 was not detected in your sample. A negative result is presumptive, meaning it is not certain that you do not have COVID-19. You may still have COVID-19 and you may still be contagious. There is a higher chance of false negative results with antigen tests compared to laboratory-based tests such as PCR. If you test negative and continue to experience COVID-19-like symptoms, (e.g., fever, cough, and/or shortness of breath) you should seek follow up care with your health care provider.

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 Result



If the control (C) line is not visible, the test is invalid. Re-test with a new swab and new test device. If the problem persists, contact Genabio by email at info@genabio.com or by phone at 1-800-614-3365.

How to Use This Test

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

If you test negative but continue to have symptoms of COVID-19, and both your first and second tests are negative, you may not have COVID-19, however you should follow-up with your healthcare provider.

If your test is positive, then proteins from the virus that causes COVID-19 have been found in your sample and you likely have COVID-19.

Users may report test result(s) at Genabio.com under "Report Test Results" – this voluntary reporting helps public health teams understand COVID-19 spread in your area and across the country and informs public health decisions.

Clinical Performance

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 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 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. 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 following table:

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	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%)	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%)	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.

Clinical performance characteristics of the Genabio COVID-19 Rapid Self-Test Kit were evaluated in a prospective study conducted at two (2) investigational sites throughout the United States to validate the

test for detection of SARS-CoV-2 in subject-collected anterior nasal (AN) swab samples The study evaluated the test's performance in symptomatic individuals (those suspected of COVID-19) within 7 days of symptom onset. Each enrolled subject was provided a Genabio COVID-19 Rapid Self-Test Kit. Under the observation of a clinical site staff member trained as a proctor, subjects fourteen (14) years and older independently collected an anterior nasal sample, conducted the test according to the IFU, interpreted and reported their self-test result. The parents of subjects two (2) to fourteen (14) years of age collected the anterior nasal sample, conducted the test, interpreted, and recorded the test result for the child. The Genabio COVID-19 Rapid Self-Test Kit results were compared to highly sensitive molecular FDA EUA-authorized SARS-CoV-2 assays to determine test performance.

A total of 72 symptomatic and 109 asymptomatic participants were enrolled in this study. Valid Genabio COVID-19 Rapid Self-Test Kit and RT-PCR results were obtained for 72 symptomatic participants. Among symptomatic participants, Genabio COVID-19 Rapid Self-Test Kit when conducted by a lay user correctly identified 91.89% of positive samples, and 100% of negative samples. The performance is shown in the following table.

Performance of Genabio COVID-19 Rapid Self-Test Kit

Genabio COVID-19 Antigen Rapid Test	Comparator Method		
	Positive	Negative	Total
Positive	34	0	34
Negative	3	35	38
Total	37	35	72
Positive Agreement: (34/37) 91.89%; 95% Confidence Interval: 78.70% to 97.21%			
Negative Agreement: (35/35) 100%; 95% Confidence Interval: 90.11% to 100.00%			

Performance stratified by days since symptom onset

Days Since Symptom Onset	RT-PCR Positive	Genabio test Positive	Positive Percentage Agreement
1	9	8	88.89%
2	6	5	83.33%
3	3	3	100.00%
4	4	4	100.00%
5	5	5	100.00%
6	5	5	100.00%
7	5	4	80.00%
All specimens	37	34	91.89%

Performance Characteristics

Analytical Sensitivity: Limit of Detection (LoD)

The Limit of Detection (LoD) of the Genabio COVID-19 Rapid Self-Test Kit was determined using serial dilutions of the characterized heat-inactivated SARS-CoV-2 (USA-WA1/2020). Contrived samples were prepared by spiking the strain into pooled human nasopharyngeal and anterior nasal swab clinical matrix obtained from individuals who tested negative for SARS-CoV-2 by RT-PCR. The spiked sample preparation was pipetted onto a swab and subsequently tested per the IFU. All samples were tested in 3 replicates. The lowest concentration at which all 3 replicates were positive was treated as the tentative LoD. The LoD was confirmed by testing 20 replicates with concentrations at the tentative limit of detection. The final LoD of the Genabio COVID-19 Rapid Self-Test Kit was determined to be 1.78×10^{4} $TCID_{50}$/mL resulting in positive detection of 20 replicates.

Based upon the testing procedure for this study the LoD of 1.78×10^{4} $TCID_{50}$/mL equates to 4.45×10^{3} $TCID_{50}$/swab

OMICRON TESTING

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. Specimen pools were prepared by the RADx team using pooled clinical samples from currently circulating Omicron strains and tested by RADx® to assess performance with the Omicron variant. Results from this dilution series cannot be compared to any devices tested with a different specimen pool 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 Genabio COVID-19 Rapid Self-test Kit detected 100% of live virus Omicron samples at a Ct-value of 26.7 (n=5). Testing was also compared to additional EUA authorized OTC antigen tests (Assay #1 and Assay #2). Omicron dilutions at lower viral concentrations (Ct-values equal to or greater than 27.7) were not detected by the Genabio COVID-19 Rapid Self-test Kit in this study.

Omicron Pool – Live Omicron Clinical Samples	Average N2 Ct (n=9)	Assay #1 Percent Positive (n=5)	Assay #2 Percent Positive (n=5)	Genabio COVID-19 Rapid Self-test Kit Percent Positive (n=5)
Dilution 1	18.0	100	100	100
Dilution 2	19.4	100	100	100
Dilution 3	20.0	100	100	100
Dilution 4	21.5	100	100	100
Dilution 5	23.0	100	100	100
Dilution 6	24.4	100	100	100
Dilution 7	25.4	0	0	100
Dilution 8	26.7	0	0	100
Dilution 9	27.7	0	0	0
Dilution 10	28.7	0	0	0
Dilution 11	29.8	0	0	0

Analytical Specificity: Microbial Cross Reactivity and Interference

Cross-reactivity and interference studies of the Genabio COVID-19 Rapid Self-Test Kit 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 (9 bacteria, 1 yeast, and 17 viruses) were tested in both the absence and presence of inactivated SARS-CoV-2 (isolate USA-WA1/2020) at 3x LoD. All testing samples were prepared in negative clinical nasopharyngeal and anterior nasal matrix. Cross-reactivity was observed with SARS-CoV Urbani. No cross reactivity or interference was observed for any other organisms and viruses tested at the concentrations as shown in the table below.

Microbial Cross-reactivity and Interference Study Results

Pathogens Added	Concentration Tested	SARS-CoV-2 Negative Sample	SARS-CoV-2 Positive Sample
Influenza A H1N1	5.20E+07$CEID_{50}$/ml	Negative	Positive
Influenza B	1.60E+06$CEID_{50}$/ml	Negative	Positive
Rhinovirus	2.80E+08$TCID_{50}$/ml	Negative	Positive
Adenovirus (Type 1)	5.00E+07 $TCID_{50}$/ml	Negative	Positive
Adenovirus (Type 2)	8.89E+09$TCID_{50}$/ml	Negative	Positive
Enterovirus 71	2.80E+07$TCID_{50}$/ml	Negative	Positive
Respiratory syncytial virus	1.60E+08$TCID_{50}$/ml	Negative	Positive
Coronavirus (OC43)	1.60E+06$TCID_{50}$/ml	Negative	Positive
Coronavirus (NL63)	1.17E+05$TCID_{50}$/ml	Negative	Positive
Coronavirus (229E)	2.80E+06$TCID_{50}$/ml	Negative	Positive
MERS	4.17E+05$TCID_{50}$/ml	Negative	Positive

Pathogens Added	Concentration Tested	SARS-CoV-2 Negative Sample	SARS-CoV-2 Positive Sample
SARS, Urbani	1.00E+05 $TCID_{50}$/ml	Positive	-
SARS, Urbani	3.70E+03 $TCID_{50}$/ml	Negative	-
Human Metapneumovirus	1.05E+05$TCID_{50}$/ml	Negative	Positive
Parainfluenza virus (Type 1)	1.60E+06$TCID_{50}$/ml	Negative	Positive
Parainfluenza virus (Type 2)	1.60E+06$TCID_{50}$/ml	Negative	Positive
Parainfluenza virus (Type 3)	8.90E+07$TCID_{50}$/ml	Negative	Positive
Parainfluenza virus (Type 4b)	2.80E+06$TCID_{50}$/ml	Negative	Positive
Legionella pneumophila	1.42E+09cfu/ml	Negative	Positive
Haemophilus influenzae	1.90E+08cfu/ml	Negative	Positive
Streptococcus pneumoniae	3.80E+07cfu/ml	Negative	Positive
Streptococcus pyogenes	1.50E+09cfu/ml	Negative	Positive
Candida albicans	2.10E+07cfu/ml	Negative	Positive
Bordetella pertussis	6.43E+08cfu/ml	Negative	Positive
Mycoplasma pneumoniae	9.00E+06cfu/ml	Negative	Positive

Pathogens Added	Concentration Tested	SARS-CoV-2 Negative Sample	SARS-CoV-2 Positive Sample
Chlamydia pneumoniae	1.25E+07IFU/ml	Negative	Positive
Staphylococcus. aureus	2.80E+07 cfu/ml	Negative	Positive
Staphylococcus. epidermidis	3.20E+08cfu/ml	Negative	Positive
Pooled human nasal wash	100%	Negative	Positive

To estimate the likelihood of cross-reactivity with SARS-CoV-2 or organisms that were not available for wet testing, in-silico analysis was used to assess the degree of protein sequence homology. Human Coronavirus HKU1 nucleocapsid phosphoproteins were analyzed and results indicate low homology between proteins, but cross-reactivity cannot be ruled out. No homologous proteins were identified in, *Mycobacterium tuberculosis* or *Pneumocystis jirovecii*. Cross-reactivity with these organisms is highly unlikely but cannot be completely ruled out

• Human Coronavirus HKU1 shows 37% homology across 82% of the SARS-CoV-2 nucleocapsid sequence, which is relatively low. However, cross-reactivity cannot be ruled out.

• *Mycobacterium tuberculosis* shows no protein sequence homology with SARS-CoV-2 nucleocapsid sequence. Therefore, while cross-reactivity is highly unlikely, it cannot be completely ruled out.

• *Pneumocystis jirovecii* shows no protein sequence homology with SARS-CoV-2 nucleocapsid sequence. Therefore, while cross-reactivity is highly unlikely, it cannot be completely ruled out.

Endogenous/Exogenous Interfering Substances and Cross Reactivity

Endogenous and exogenous Interference of the Genabio COVID-19 Rapid Self-Test Kit was evaluated by testing a panel of 20 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 SARS-CoV-2) and negative samples were tested with the addition of potentially interfering substances and tested in three replicates. Based on the data generated by this study, the potentially endogenous/exogenous interfering substances listed in the table below do not affect the performance of the Genabio COVID-19 Rapid Self-Test Kit. at the concentrations tested.

Potential Endogenous/Exogenous Interfering Substances

Endogenous Substances Tested	Test Concentration	SARS-CoV-2 Negative Sample	SARS-CoV-2 Positive Sample
Whole Blood	4%	Negative	Positive
Mucin	0.5%	Negative	Positive
Chloraseptic	1.5 mg/mL	Negative	Positive

Endogenous Substances Tested	Test Concentration	SARS-CoV-2 Negative Sample	SARS-CoV-2 Positive Sample
Naso GEL (NeilMed)	5% v/v	Negative	Positive
Nasal Drops (Phenylephrine)	15% v/v	Negative	Positive
Afrin (Oxymetazoline)	15% v/v	Negative	Positive
CVS Nasal Spray	15% v/v	Negative	Positive
NasalCrom (Cromolyn)	15% v/v	Negative	Positive
Zicam	5% v/v	Negative	Positive
Homeopathic (Alkalol)	1:10 dilution	Negative	Positive
Sore Throat Phenol Spray	15% v/v	Negative	Positive
Tobramycin	4 µg/mL	Negative	Positive
Mupirocin	10 mg/mL	Negative	Positive
Fluticasone Propionate	5% v/v	Negative	Positive
Tamiflu (Oseltamivir Phosphate)	5 mg/mL	Negative	Positive
Safeguard Bar Soap	5% w/v	Negative	Positive
SoftSoap Liquid Hand Soap	5% v/v	Negative	Positive
Purell Hand Sanitizer	5% v/v	Negative	Positive
CeraVe Body & Hand Lotion	5% w/v	Negative	Positive
Dionis Hand Cream	5% w/v	Negative	Positive

High-dose Hook Effect

SARS-CoV-2 cultured virus was spiked into pooled negative clinical matrix. SARS-CoV-2 cultured virus did not show hook effect at the concentration of 6.45×10^{5} $TCID_{50}$/mL of heat-inactivated virus.

Index of Symbols

REF	Catalogue Number	IVD	In Vitro Diagnostics Medical Device
LOT	Lot Number (Batch Code)	Σ	Tests Per Kit
	Use By (Expiration Date)		Manufacturer
	Temperature Limitations (Storage Temperature)	UDI	Unique Device Identifier
	One Time Use (Single Use Only)		Consult Quick Reference Instructions

Manufacture Contact Information

Made in China

Manufactured for Genabio Diagnostics Inc.

19b Crosby Dr. Ste 220, Bedford MA 01730

For orders please contact: sales@genabio.com

For any other questions, please contact via email: info@genabio.com, or via phone: 1-800-614-3365.

GBD210613 Rev8, Effective May 2025