

# GenBody COVID-19 Ag Home Test

## SARS-CoV-2 Antigen Self-test

! In case of failure to test according to the instructions for use accurately, please get assisted from someone professional can test according to the instructions for use accurately.

Refer to the  
images and  
instructions below  
before the test.



### 01 Before the test

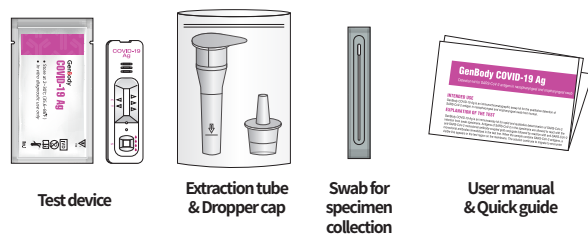
Wash hands with soap or hand sanitizer  
and dry thoroughly before the test.



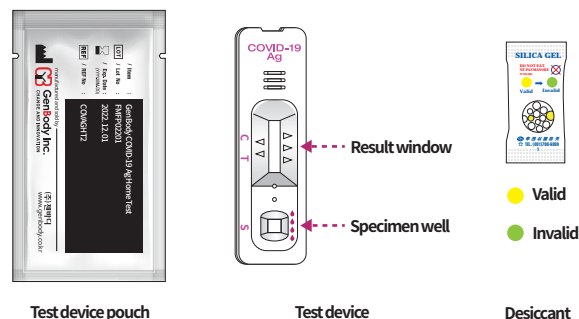
### 02 Preparation

! All components must be tested in a flat and clean place.

Check the kit components before the test.



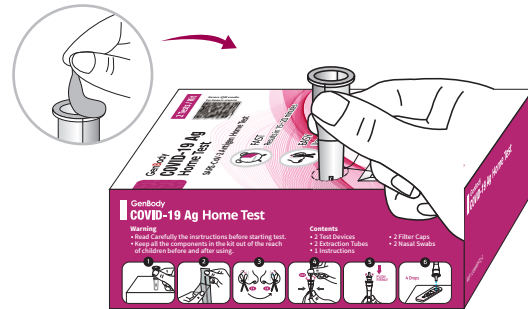
Check the expiry date on the back of the test device pouch and the color of the desiccant enclosed in the device pouch. Do not use the test device if the expiry date has passed.



### 03 Specimen collection

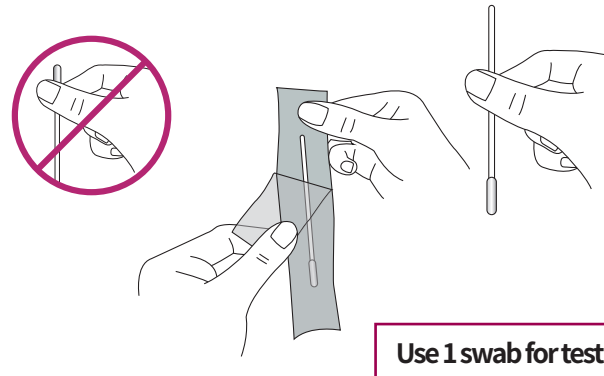
- ! Do not eat the solution in the extraction tube or contact the skin or eyes.
- ! If you don't insert the extraction tube into the box hole, the extraction tube may collapse.

Remove the lid of the extraction tube and place it in the extraction tube box hole.



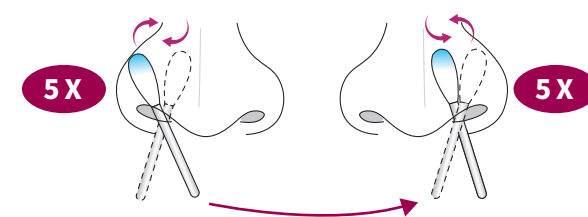
! Caution: be careful not to touch the head of the swab when removing it.

Take out the swab by peeling the packaging off for specimen collection.



! Be careful not to put the swab too deep. Make sure to collect the specimen in the both sides of the nose.

Put the soft head of the swab in the nose about 1.5 cm deep and slowly rub the inside wall five times for 15 seconds with medium pressure. Repeat the process to the another nose.



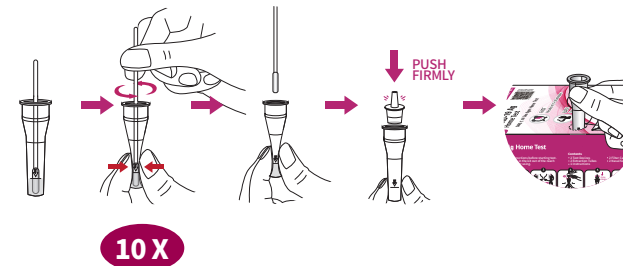
! Specimen of both nostrils should be collected with one swab for the test accuracy.

! Collect the specimen with a mirror if the specimen collection is not easy.

### 04 Test procedure

! Do not eat the solution in the extraction tube or contact the skin or eyes.

Prepare the extraction tube, put the swab in it, and press both sides of the tube and rotate the swab at least 10 times for squeezing it. Then press down on the swab and remove it from the extraction tube. Close the filter cap and plug in into the box hole. Do not use solutions that have not been sampled.



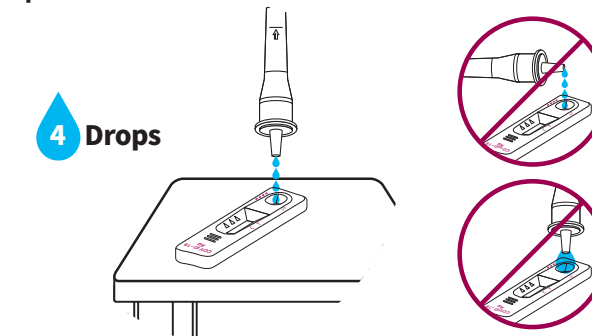
! Do not touch the result window or the specimen well of the test device.

Take the test device out from its pouch and place it on a flat surface. Check the color of the desiccant enclosed in the device pouch.

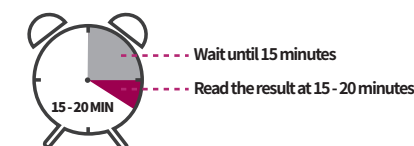


! Do not squeeze all the solution out of the extraction tube.

Stand the extraction tube with the closed dropper cap upside down vertically and add **ONLY 4 drops** of the solution with **carefully squeezing** into the specimen well of the device.

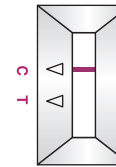


Please wait 15 minutes and read the result.  
Do not read after 20 minutes.



### 05 Test interpretation

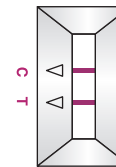
#### COVID-19 Negative (-)



ONLY one band in the control line (C). It means that the COVID-19 antigen was not detected in the specimen of the test.

! Negative result does not rule out COVID-19. You should continue to monitor for COVID symptoms and get tested at the first sign of any symptoms.

#### COVID-19 Positive (+)

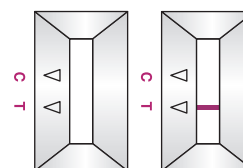


Two bands are appeared in the control line (C) and the test line (T). Any faint visible reddish-purple test (T) line with the control line (C) should be read as positive.

It means that SARS-CoV-2 antigen is detected in the specimen, and there is a possibility of infection with SARS-CoV-2.

! Confirmation PCR test will not be required after a positive RAT. Individual states and territories will provide further information on how a positive RAT will be recorded. If your test result is positive, contact the health authority in your relevant state or territory for guidance on confirmation testing if necessary. Seek medical advice if you feel sick.

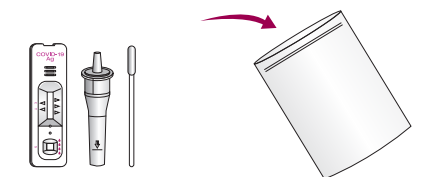
#### Invalid



If the control line (C) does not appear, it means the invalid result. Re-test with a new device and new swab.

! You may have performed the test incorrectly. Carefully read the Instructions for Use and repeat the test. If your test result is still invalid, please contact your doctor or a COVID-19 test center.

### 06 Disposal



Place all used kit components and the swab samples back in the pouch and dispose the pouch in household waste.

FOR TECHNICAL HELP, PLEASE CONTACT:

Technical Support  
Nature's Family Australia Pty Ltd  
Tel: 1880 935 970  
\*Hours" 9am - 7pm (AEST) 7 days per week

GenBody COVID-19 Ag Home Test

INTENDED USE

The GenBody COVID-19 Ag Home Test is a single-use rapid lateral flow chromatographic immunoassay intended to detect nucleocapsid protein antigen from the SARS-CoV-2 virus that causes COVID-19 in anterior nares (AN) nasal swab samples that are self-collected by an individual aged 14 years or older or are collected by an adult from an individual age 2 years and older within the first 6 days of the onset of symptoms.

EXPRANATION OF THE TEST

GenBody COVID-19 Ag Home Test is an immunoassay kit for rapid and qualitative determination of SARS-Cov-2 infection from nasal swab specimens. Antigens of SARS-CoV-2 in the specimens are allowed to react with the anti-SARS-CoV-2 monoclonal antibody-coupled gold conjugate followed by reaction with anti-SARS-CoV-2 monoclonal antibodies immobilized in the test line. When the sample contains SARS-CoV-2 antigens, a visible line appears in the test region on the membrane. The solution continues to migrate to encounter a control reagent that binds a control conjugate, thereby producing another band in the control region.

KIT COMPONENTS

Note: This kit comes in packs of 2 tests.

- 1. Test device individually foil-pouched with a desiccant
- 2. Extraction tube
- 3. Dropper cap
- 4. Sterilized nasal swab
- 5. Instructions for use

MATERIALS REQUIRED BUT NOT PROVIDED

- 1. Mask and gloves
- 2. Watch or timer

SAMPLE REQUIREMENTS

Applicable to anterior nasal swab samples. It is recommended that the samples are tested immediately at the time of sample collection.

WARNING AND PRECAUTIONS

- 1. Exposure to humidity may decrease the stability of the test. The test should be performed immediately after removing it from the foil pouch.
- 2. For in Vitro Diagnostics use only.
- 3. Test devices are single use only and should be discarded after use. Do not re-use the test device.
- 4. Collected sample should be prepared in accordance with the procedure of nasal sample collection and tested as soon as possible.
- 5. Ensure the test device and prefilled solution in the tube reach room temperature (15-30°C) before testing (15 – 30 min).
- 6. Do not read results before 15 minutes or after 20 minutes as it may cause false negative and false positive results.
- 7. False negative test results (i.e., an existing infection is not detected) may occur if testing is not performed within the first 7 days of symptom onset as the antigen level in the specimen may be too low for the test to detect.
- 8. Confirmation PCR test will not be required after a positive RAT. If your test result is positive, contact the health authority in your relevant state or territory for guidance on confirmation testing if necessary. Seek medical advice if you feel sick.
- 9. You should not use the test result as the sole basis for treatment. Your healthcare provider should consider your test results, along with your recent exposure, history, clinical signs, and symptoms,

and with a molecular test confirmation, if necessary for patient management.

- 10. Positive test results do not rule out co-infections with other pathogens. Negative test results are not intended to rule-in other non-SARS viral or bacterial infections.
- 11. A negative test result may occur if the level of antigen in a sample is below the detection limit of the test or if the sample was collected improperly.
- 12. Negative results should be treated as presumptive only and may not mean you are not infectious. If you are experiencing any COVID symptoms you must seek immediate further testing.
- 13. Even with a negative result, you may still be infectious. If you are showing symptoms, you must seek immediate further testing by PCR.
- 14. Test performance depends on the amount of viral antigen in the specimen and may or may not correlate with results performed by cultured virus on the same sample.
- 15. Dispose of the kit components in your household waste (not recycling) or according to your local guidelines. Remaining liquid in the tube should not be released into the drainage system or water bodies.
- 16. The test is less reliable in the later phase of infection and in asymptomatic individuals.
- 17. A negative result does not rule out infection with another type of respiratory virus.
- 18. A positive result cannot necessarily determine whether a person is infectious.
- 19. Recommend repeat testing (e.g. within 1-3 days) if there is an ongoing suspicion of infection, being in a high risk setting or where there is an occupational risk or other requirement.

PERFORMANCE CHARACTERISTICS

Variants

GenBody COVID-19 Ag Home Test could detect Alpha, Beta, Gamma, Delta, and Omicron variants.

Limit of Detection

The Limit of Detection (LoD) of the SARS-CoV-2 Ag Home Test kit is confirmed as 1.42 X 10<sup>2</sup> TCID<sub>50</sub>/mL.

Clinical performance

The clinical performance characteristics of the GenBody COVID-19 Ag Home Test using anterior nasal swab specimen were evaluated in South Korea and the United States against an RT-PCR molecular assay as a comparator method. Subjects self-collected and self-tested using the GenBody COVID-19 Ag Home Test in a simulated home setting utilizing only the labeling provided with the test. Total 613 subjects were enrolled in this study. The GenBody COVID-19 Ag Home Test when conducted by a lay user correctly identified 89.23% of positive samples (116/130) and 99.59% of negative samples (481/483).

Cross-reactivity and Interference Study

The GenBody COVID-19 Ag Home Test does NOT differentiate between SARS-CoV and SARS-CoV-2.

The following cross-reactants and microorganisms had no impact on the performance of the GenBody COVID-19 Ag Home Test:

Adenovirus (C1 Ad.71), Enterovirus D68, Human Metapneumovirus (hMPV), Influenza A H1N1 (New Cal/20/99), Influenza B (Florida/02/06), Human coronavirus 229E, Human coronavirus OC43, Human coronavirus NL63, MERS-coronavirus, SARS-coronavirus, Parainfluenza virus 1/2/3/4, Influenza A virus, Influenza B virus, Enterovirus, Respiratory Syncytial Virus- Type A, Respiratory Syncytial Virus- Type B, Rhinovirus-Type 1A, Rhinovirus-Type 14, Rhinovirus-Type 42, *Haemophilus influenzae*, *Bordetella pertussis*, *Candida albicans*, *Chlamydia pneumoniae*, *Legionella*

*pneumophila*, *Mycobacterium tuberculosis*, *Mycoplasma pneumoniae*, *Pseudomonas aeruginosa*, *Staphylococcus epidermidis*, *Staphylococcus aureus*, *Streptococcus pneumoniae*, *Streptococcus pyogenes*, *Streptococcus salivarius*, Cytomegalovirus, Epstein-Varr Virus, Varicella Zoster Virus, Parvovirus B19, Human Immunodeficiency Virus-1, Human Immunodeficiency Virus-2, Hepatitis C Virus, Hepatitis B Virus Genotype-A, Hepatitis B Virus Genotype-B, Hepatitis B Virus Genotype-C, Hepatitis B Virus Genotype-D, Hepatitis B Virus Genotype-E, Hepatitis B Virus Genotype-F, Hepatitis B Virus Genotype-H, Herpes Simplex Virus-1, Herpes Simplex Virus-2, Escherichia coli, Human Adenovirus type 1, Adenovirus type 3, Adenovirus type 5, Adenovirus type 7, Adenovirus type 8, Adenovirus type 11, Adenovirus type 18, Adenovirus type-23.

Interference Study

The following potentially interfering substances had no impact on the performance of the GenBody COVID-19 Ag Home Test: Viral Transport Medium (VTM), Sodium citrate, EDTA, Heparin, Hemoglobin, Albumin, conjugated bilirubin, Lipid standard (triglyceride), Anti-nuclear antibody, Whole blood, Mouth wash, Phenylephrine, Acetylsalicylic acid, Beclomethasone, Benzocaine, flunisolide, Guaicol glyceryl ether, Menthol, Oxymetazoline, Tobramycin, Zanamivir, Oseltamivir phosphate, mucous.

STORAGE AND EXPIRATION

- 1. GenBody COVID-19 Ag Home Test kit should be stored between 2 to 30°C (35.6 to 86°F).
- 2. Kit components in the GenBody COVID-19 Ag Home Test kit are stable until the expiration date printed on the label.

REF

COVAGHT2, COVAGHT2-1

CONTACT INFORMATION

If you gave questions about your test kit, including hot to use it or to make an enquiry or complaint, you can call Nature’s Family on:

1800 935 970 (9 am to 7 pm AEST, 7 days/week)

Australia Distributor / Agent



Nature’s Family Australia Pty Ltd (ABN: 97 111 180 379)  
Unit W2/11-13 Orion Rd Lane Cove NSW 2066 Australia

Manufacturer



GenBody Inc.  
3-18, Eopseong 2-gil, Seobuk-gu, Cheonan-si, Chungcheongnam-do, 31077, Republic of Korea  
Tel: +82-41-523-8993 (International)  
Email: [contact@genbody.co.kr](mailto:contact@genbody.co.kr)  
Website: <http://www.genbody.co.kr>

Additionally, you may wish to report poor performance or usability issues directly to the Therapeutic Goods Administration (TGA) via the Medical Device Incident Reporting scheme , email [iris@tga.gov.au](mailto:iris@tga.gov.au) or call 1800 809 361  
To contact your local state/territory health department.  
Visit on the following link:  
<https://www.health.gov.au/about-us/contact-us/local-state-and-territory-health-departments>

LOCAL STATE AND TERRITORY HEALTH DEPARTMENTS

Contact details and websites of the local state and territory health departments.

Australian Capital Territory Department of Health	Business hours 02 5124 9213 Coronavirus Helpline (8 am to 8 pm daily) 02 6207 7244	<a href="https://health.act.gov.au">https://health.act.gov.au</a>
New South Wales Department of Health	General enquiries 1300 066 055 Coronavirus hotline Services	<a href="https://www.health.nsw.gov.au">https://www.health.nsw.gov.au</a>
Northern Territory Department of Health	General enquiries 08 8922 8044 Coronavirus hotline (National helpline) 1800 020 080	<a href="https://health.nt.gov.au">https://health.nt.gov.au</a>
Queensland Department of Health	13HEALTH 13 432 584 Coronavirus hotline: 134COVID 134 268	<a href="https://www.health.qld.gov.au">https://www.health.qld.gov.au</a>
South Australian Department of Health	General enquiries 1300 232 272 Coronavirus hotline (9am to 5pm daily) 1800 253 787	<a href="https://www.sahealth.sa.gov.au/wps/wcm/connect/Public+Content/SA+Health+Internet">https://www.sahealth.sa.gov.au/wps/wcm/connect/Public+Content/SA+Health+Internet</a>
Tasmanian Department of Health	General enquiries 1300 135 513 Public Health Hotline (coronavirus) 1800 671 738	<a href="https://www.health.tas.gov.au">https://www.health.tas.gov.au</a>
Victorian Department of Health	Department of Health and Human Services 1300 650 172 Victorian coronavirus hotline (24/7) 1800 675 398	<a href="https://www.dhhs.vic.gov.au">https://www.dhhs.vic.gov.au</a>
Western Australian Department of Health	General enquiries 08 9222 4222 Coronavirus hotline: 13COVID (8am to 6pm, Mon–Fri) 1800 595 206	<a href="https://www.health.wa.gov.au/Articles/A_E/Contact-details-for-population-public-health-units">https://www.health.wa.gov.au/Articles/A_E/Contact-details-for-population-public-health-units</a>

In vitro diagnostic medical device	Do not re-use	Contains sufficient for <n> tests	Caution	Consult instructions for use	Batch code	Catalog number	Use-by date	Temperature limit