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.

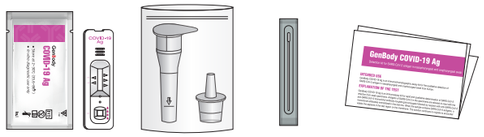
01 Before the test

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

02 Preparation

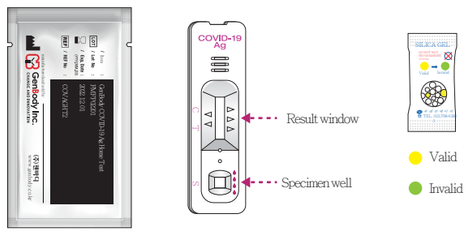
All components must be tested in a flat and clean place.

Check the kit components before the test.



Test device | Extraction tube & Dropper cap | Swab for specimen collection | User manual & Quick guide

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.



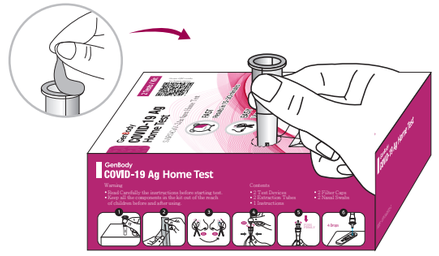
Test device pouch | Test device | Desiccant

03 Specimen collection

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

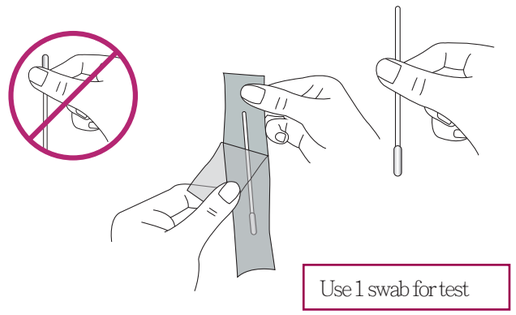
If you don't insert the extraction tube into the box hole, the extraction tube may collapse.

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.

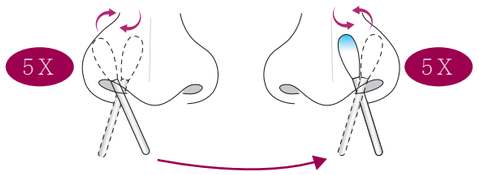
Take out the swab by peeling the packaging off for specimen collection.



Use 1 swab for test

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.



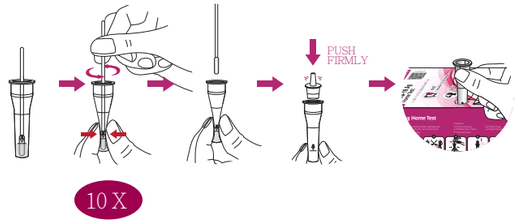
Specimen of both nostrils should be collected with one swab for the test accuracy.

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

04 Test procedure

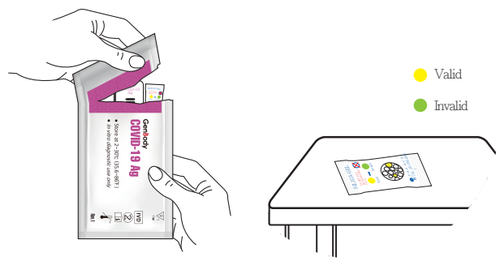
Do not eat the solution in the extraction tube or contact the skin or eyes.

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.



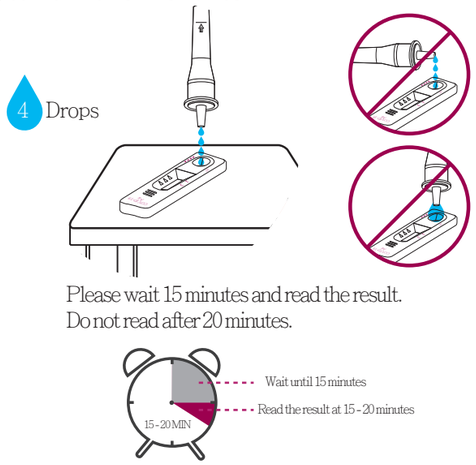
Do not touch the result window or the specimen well of the test device.

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

ONLY one band on the control line (C)

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.

Two bands on the both of the control line (C) and the test line (T)

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.

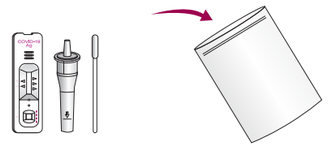
It means that SARS-CoV-2 antigen is detected in the specimen, and there is a possibility of infection with SARS-CoV-2. Be sure to visit a medical center for a molecular test.

No band on the control line (C)

Invalid

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

06 Disposal



If both the control line (C) and the test line (T) appear (positive), the materials used for he test, such as the device, extraction solution and swab, are sealed with an extraction solution bag and submitted at the time of visiting a medical institution to be disposed of as COVID-19 quarantine medical waste. If only the control line (C) appears (negative), seal the components used in the test with an extraction tube bag and dispose of them as household waste.

Contact

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Manufactured by GenBody Inc.
CHANGE AND INNOVATION

GenBody COVID-19 Ag Home Test

INTENDED USE

GenBody COVID-19 Ag Home Test is a lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein from SARS-CoV-2 from individual’s nasal specimen with or without COVID-19 symptoms.

EXPLANATION OF THE TEST

GenBody COVID-19 Ag 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.

MATERIALS PROVIDED

1. Test device individually foil-pouched with a desiccant
2. Extraction tube & Disposable dropper cap in the bag
3. Sterilized nasal swab
4. Instructions for use

MATERIALS REQUIRED BUT NOT PROVIDED

1. Mask & gloves
2. Watch or timer

ASSAY PROCEDURE

1 Before starting

Wash or sanitize your hands and dry completely.

2 Prepare for the test

1) Check components before test.
2) Check the expiry on the back of the test device pouch. Please don’t use the device that are expired.
*Check the color of the desiccant enclosed in the device pouch.

3 Nasal specimen collection

1) Remove the lid of the extraction tube and plug it into the extraction tube tray.
2) Unpack the swab by opening the packaging for sample collection.
3) Put the soft head of the swab in the nose about 1.5cm deep and slowly rub the inside wall for five times for 15 seconds with medium pressure.
4) Repeat the another nostril using the same swab.

! For the accuracy of the test, Repeat another nostril using the same swab.

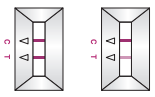
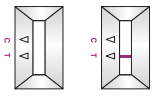
4 Test procedure

1) Prepare the extraction tube, put the swab out of the nose, and press both sides of the tube and rotate it at least 10 times for squeezing the swab. Then press down on the swab and remove it from the extraction tube and close with the filter cap.
2) Unpack the test device pouch and place it on a flat surface and check the color of desiccant.
3) Turn the extraction tube with the filter cap over and add 4 drops of solution into the specimen well of the device.

5 Interpret results

Results should be read between 15 - 20 minutes after the addition of the specimen to the test device and refer to INTERPRETATION OF THE RESULT. Do not read after 20 minutes.

INTERPRETATION OF THE RESULTS

RESULTS	INTERPRETATION
	Negative result: ONLY one band in the control line (C). It means that the SARS-CoV-2 virus antigen was not detected in your specimen in this test.
	Positive result: Two bands are appeared in the test line (T) and control line (C). Any faint visible reddish purple test (T) line with control (C) line 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. Be sure to visit a medical center for a molecular test
	Invalid: If a red color band does not appear in the control line (C) within 20 minutes, the result is considered invalid regardless of any shade of a reddish purple test line (T) appears. If the test is invalid, a new test should be performed with a new device and new swab.

WARNING

1. Exposure to humidity may decrease the stability of the reagents. The test should be performed immediately after removing the device from the foil pouch.
2. For in vitro diagnostic use only.
3. Test devices are single use only and should be discarded after use. Do not re-use the test device.
4. Collected specimen should be prepared in accordance with the procedure of nasal specimen collection and tested as soon as possible.
5. Add the fixed volume (4 drops) to the center of specimen well of the test device.
6. Bring the test kit and extraction solution at room temperature (15-30° C) prior to testing (15 - 30min).
7. Keep testing time because it causes false negative and false positive.
8. It is not possible to determine whether the virus is infected or not only with the result of this product, and the medical doctor must make the final judgment, together with the clinical symptoms, etc.
9. 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.
10. 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.
11. This test detects both symptomatic and non-symptomatic SARS-CoV-2 infection. 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.
12. All components should be tested in clean place.
13. Do not eat the solution in the extraction tube and not be allowed to the skin or eyes.
14. Be careful not to touch the head of the swab when removing it.
15. Do not put the swab too deep into your nose.
16. Do not touch the result window and the specimen well of the test device.
17. The test should be placed and performed on the flat surface.
18. The device can be tested if the color of silica gel is yellow and the device cannot be tested if the color of silica gel is green.
19. Collect the specimen with a mirror if the specimen collection is not easy.
20. If you don’t insert the extraction tube into the box hole, the extraction tube may collapse.
21. Put the swab that has been sampled in the extraction tube and mix it well before using it. Do not use solutions that have not been sampled.
22. When dropping the solution in the extraction tube into the sample well of device, the filter cap must be closed.
23If you cannot use it correctly according to the instructions, seek help from someone who can use it correctly.
24. If both the control line (c) and the test line (t) appear (positive), seal the substances used for the test with enclosed extraction tube bag, submit them to medical clinics. If only control line (c) appears(negative), seal the items used for the test with enclosed extraction tube bag and treat them as household waste.

STORAGE & EXPIRATION

1. GenBody COVID-19 Ag kit should be stored between 2 to 30 ° C (35.6 to 86 ° F).
2. Expiration date of this kit is 24 months after its manufacture date.

REF: COVAGHT2-1

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IVD		Σ	!		LOT	REF		
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

PREFORMANCE CHARACTERISTICS

1. Limit of Detection (LoD):

The Limit of Detection (LoD) of the GenBody Ag Home Test was determined using serial dilutions of the heat-inactivated SARS-CoV-2 (USA-WA1/2020). The material was frozen at a concentration of $TCID_{50}$ of 3.55 x 105 / mL. The GenBody Ag Home Test Limit of Detection was confirmed by testing the selected dilution 1.11 x 10^2 $TCID_{50}$ /mL in 20 replicates.

2. Cross-reactivity

No cross reactivity was observed among all tested microorganisms described in the below table

Microorganism	Concentration	+SARS-CoV-2			-SARS-CoV-2		
Adenovirus (e.g. C1)	3.09 x 10^8 $TCID_{50}$/mL	+	+	+	-	-	-
Enterovirus (e.g. EV68)	5.01 x 10^5 $TCID_{50}$/mL	+	+	+	-	-	-
Human Metapneumovirus (hMPV)	3.80 x 10^6 $TCID_{50}$/mL	+	+	+	-	-	-
Influenza A H1N1 (New Cal/20/99)	1.15 x 10^7 $TCID_{50}$/mL	+	+	+	-	-	-
Influenza B (Florida/02/06)	5.49 x 10^7 $TCID_{50}$/mL	+	+	+	-	-	-
Parainfluenza virus 1	9.12 x 10^8 $TCID_{50}$/mL	+	+	+	-	-	-
Parainfluenza virus 2	4.17 x 10^5 $TCID_{50}$/mL	+	+	+	-	-	-
Parainfluenza virus 3	6.61 x 10^6 $TCID_{50}$/mL	+	+	+	-	-	-
Parainfluenza virus 4A	1 x $10^{6.58}$ $TCID_{50}$/mL	+	+	+	-	-	-
Respiratory syncytial virus -Type A	3.80 x 10^6 $TCID_{50}$/mL	+	+	+	-	-	-
Rhinovirus (Type 1A)	1 x $10^{6.58}$ $TCID_{50}$/mL	+	+	+	-	-	-
Bordetella pertussis	1.13 x 10^{10} CFU/mL	+	+	+	-	-	-
Candida albicans	6.27 x 10^8 CFU/mL	+	+	+	-	-	-
Chlamydia pneumoniae	2.12 x 10^8 IFU/mL	+	+	+	-	-	-
Haemophilus influenzae	5.43 x 10^8 CFU/mL	+	+	+	-	-	-
Legionella pneumophila	1.63 x 10^{10} CFU/mL	+	+	+	-	-	-
Mycobacterium tuberculosis	6.86 x 10^7 CFU/mL	+	+	+	-	-	-
Mycoplasma pneumoniae	3.16 x 10^8 CCU/mL	+	+	+	-	-	-
Pneumocystis jirovecii (PJP) -S. cerevisiae Recombinant	3.45 x 10^8 CFU/mL	+	+	+	-	-	-
Pseudomonas aeruginosa	3.44 x 10^9 CFU/mL	+	+	+	-	-	-
Staphylococcus epidermis	9.27 x 10^9 CFU/mL	+	+	+	-	-	-
Streptococcus pneumoniae	4.16 x 10^8 CFU/mL	+	+	+	-	-	-
Streptococcus pyogenes	1.64 x 10^9 CFU/mL	+	+	+	-	-	-
Streptococcus salivarius	8.17 x 10^8 CFU/mL	+	+	+	-	-	-
MERS-coronavirus	3.55 x 10^5 $TCID_{50}$/mL	+	+	+	-	-	-
Human coronavirus 229E	4.17 x 10^5 $TCID_{50}$/mL	+	+	+	-	-	-
Human coronavirus OC43	1.26 x 10^6 $TCID_{50}$/mL	+	+	+	-	-	-
Human coronavirus NL63	1.41 x 10^5 $TCID_{50}$/mL	+	+	+	-	-	-
SARS-coronavirus (in PBS)	1 x 10^8 PFU/mL	+	+	+	-	-	-
SARS-coronavirus (Vero E6 Cell DMEM)	1 x 10^8 PFU/mL	+	+	+	-	-	-
Pooled human nasal wash	100%	+	+	+	-	-	-
Human coronavirus HKU1	N/A	Not Tested			Not Tested		

Due to the lack of availability to Human coronavirus HKU1 in the South Korea, In silico analysis was performed via the National Center for Biotechnology Information (NCBI) Basic Local Alignment Search Tool (BLAST) to investigate the potential sequence homology between SARS-CoV-2 and HKU1 nucleocapsid phosphoproteins. The comparison analysis revealed a 36% homology across 82% of the sequences tested, thus the cross reactivity cannot be ruled out.

3. Interference

No endogenous interference or cross reactivity was observed among the substances used for this study.

Interfering Substance	Concentration (mg/dL)	Source
Viral Transport Medium (VTM)	50%	CDC Fomula
Whole blood	5%	Normal Donor
NasoGEL (NeilMed)	5% v/v	CVS
Phenylephrine (Nasal Drop)	10% v/v	CVS
Acetylsalicylic acid	20 mg/mL	CVS
Beclomethasone	0.5 mg/mL	Sigma

Interfering Substance	Concentration (mg/dL)	Source
Benzocaine (Vicks)	5%	CVS
Flunisolide	3 mg/mL	Sigma
Guaiacol glyceryl ether	20 mg/mL	Sigma
Menthol	10 mg/mL	Sigma
Oxymetazoline (Afrin)	15% v/v	CVS
Tobramycin	40 mg/mL	Sigma

Interfering Substance	Concentration (mg/dL)	Source
Zanamivir	3.3 mg/mL	Sigma
Oseltamivir phosphate (Tamiflu)	12 mg/mL	CVS
Cromolyn (Nasal Spray)	40 mg/mL	CVS
Homeopathic (Alkalol)	5% v/v	CVS
Zicam Cold Remedy	5% v/v	CVS
mucous	35%	Sigma

4. Clinical evaluation

The clinical performance of the GenBody COVID-19 Ag Home Test was determined by testing Two hundred eighty one (n=281) residual wet nasal swabs (In Republic of Korea). Upon receiving the swabs, they were placed in individual collection tubes containing 400 μL of GenBody extraction solution and mixed thoroughly as instructed in the GenBody COVID-19 Ag Home Test IFU. Each sample was then subjected to Antigen testing (GenBody COVID-19 Ag Home Test), RT-PCR (a. Real-Q 2019-nCoV Detection kit., b. Real-Q Direct SARS-CoV-2 Detection kit., BioSewoom Inc., Korea) in parallel. The table below summarizes the clinical performance analysis results on GenBody COVID-19 Ag Home Test.

Positive Percent Agreement	95.89% (95% CI: 88.46%~99.14%)
Negative Percent Agreement	100% (95% CI: 98.24%~100.00%)

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