GenBody

Date of last Revision
2023.02 (Rev.0)

COVID-19 Ag Home Test

SARS-CoV-2 Antigen
For Self-testing
For use under Emergency Use Authorization (EUA) Only
For *In vitro* diagnostic use

⚠ Carefully read the instructions before performing the test. Failure to follow the instructions may produce inaccurate test results.

STORAGE & EXPIRATION

1. GenBody COVID-19 Ag kit should be stored between 35.6 to 86 °F (2 to 30 °C). Ensure all test components are at room temperature before use.
2. Check the expiration date listed on test device pouch.
3. For the most current expiration dates of this test, please refer to: http://www.fda.gov/covid-tests.

DISPOSAL

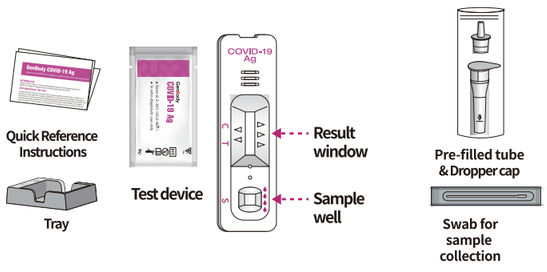
Place all used kit components and the swab samples back in the pouch and dispose the pouch in household waste.

01 Precautions Before the Test

- Wash hands with soap or hand sanitizer and dry thoroughly.
- Using the enclosed tube holder is optional. When testing with the holder, please beware of buffer spillage.
- Test Device should be used within 60 minutes after opening the pouch.

02 Preparation

1. Check all components before testing.

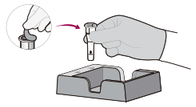


2. Open the pouch and lay the test device on a flat surface.

ⓘ **Do not touch the result window or the sample well of the test device.**

03 Sample Collection

1. Peel off the foil cover from the pre-filled tube.
2. Insert the tube upright into the tray hole.

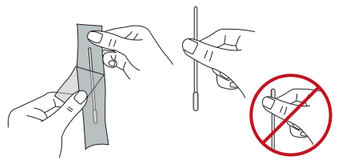
Cat# U-02	Cat# U-01, 05, 25
	

ⓘ **The type of the tray differs depending on the product catalog.**

ⓘ **Avoid exposure of your skin, eyes, nose or mouth to the solution in the tube.**

3. Blow your nose thoroughly and clear the nasal passage.

4. Remove the swab from the packaging



ⓘ **Do not touch swab head or lay the swab on any surface.**

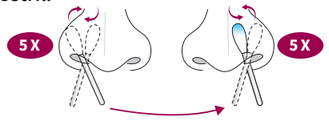
5. Collect the nasal swab sample

1) Self-collection

A nasal swab sample can be self-collected by an individual aged 14 years and older. For self-collection, insert the swab about a half inch deep into the nostril and slowly rub along the inside wall five times for 15 seconds with medium pressure. Repeat the process in the other nostril.

2) Child specimen collection

Children aged 2 to 13 years should be tested by an adult. Gently insert the entire tip of the swab head into the child's nostril (½ to ¾ of an inch). With children, the maximum depth of insertion may be less than ¾ of an inch and you may need a second person to hold the child's head while swabbing. Slowly rub along the inside wall five times for 15 seconds and repeat the process in the other nostril.



ⓘ **For test accuracy, make sure to collect sample from both nostrils.**

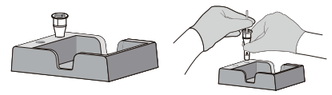
ⓘ **A false negative result may occur if the nasal swab specimen is not properly collected.**

ⓘ **Wear a face mask if swabbing others.**

ⓘ **DO NOT insert the swab any deeper if you feel resistance or pain.**

04 Test Procedure

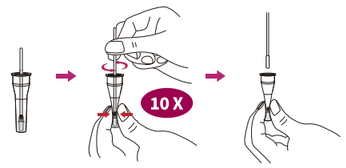
1. After collecting the sample with the swab, insert the swab into the pre-filled tube.
2. Using both hands, carefully remove the tube and swab together.



3. Squeeze the sides of the tube and twirl the swab in the liquid at least 10 times. (A false negative result may occur if the swab is not twirled at least 10 times).

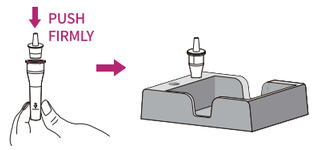
ⓘ **Inadequate sample extraction can result in incorrect results.**

4. While slowly removing the swab, continue squeezing the tube to make sure all the liquid is extracted from the swab. Discard the swab.

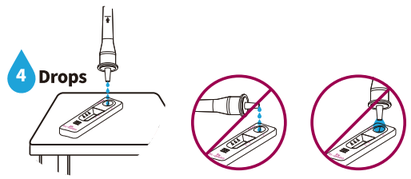


ⓘ **False negative results can occur if the specimen is not properly mixed or too vigorously mixed.**

5. Attach the filter cap by firmly pushing it vertically onto the tube and place the tube back into the tray.



6. Invert the tube and hold the sample vertically above the sample well. Carefully squeeze 4 drops of the solution into the sample well.

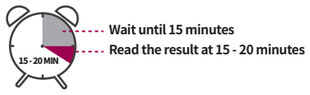


ⓘ **Adding other than recommended number of drops may result in incorrect results.**

ⓘ **Do not touch the result window or the sample well of the test device.**

ⓘ **Do not add sample to the rectangular result window.**

7. Wait 15 minutes and read the result. Do not read the result after 20 minutes. Inaccurate results may occur if the test result is read before 15 minutes or after 20 minutes.



ⓘ **False positive or false negative results can occur if test device is read before 15 minutes or after 20 minutes.**

05 Test Interpretation

Report your test result(s) at https://makemytestcount.org/ -this voluntary and anonymous reporting helps public health teams understand COVID-19 spread in your area and across the country and informs public health decisions.

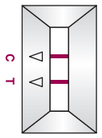
Serial (Repeat) testing

Repeat testing is needed to improve test accuracy. Please follow the table below when interpreting test results for COVID-19.

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.

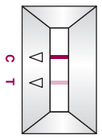
COVID-19 Positive(+)



Positive

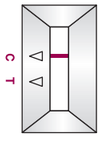
If a Control (C) line and the Test (T) line are visible, the test is positive. Any faint visible reddish purple test (T) line with the control line (C) should be read as positive.

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 and it is very likely you have COVID-19 and are contagious. Please contact your doctor/primary care physician or your local health authority immediately and 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).

COVID-19 Negative(-)



Negative

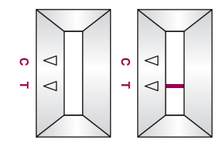
If the Control (C) line is visible, but the Test (T) line is not visible, the test is negative.

To increase the chance that the negative result or 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.

Invalid



Invalid

If the control (C) line is not visible, the test is invalid. Re-test with a new device and new swab.

GenBody COVID-19 Ag Home Test
for FDA Emergency Use Authorization (EUA) Only

INTENDED USE
The GenBody COVID-19 Ag Home Test is a lateral flow chromatographic immunoassay 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 5 days of symptom onset when tested at least twice over three days with at least 48 hours between tests, and for individuals without symptoms or other epidemiological reasons to suspect COVID-19, when tested at least three times over five days with at least 48 hours between tests.

The GenBody COVID-19 Ag Home Test does not differentiate between SARS-CoV and SARS-CoV-2.
Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen, which is generally detectable in anterior nasal (nares) swab samples during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with past medical 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 GenBody COVID-19 Ag Home Test should self-isolate and seek follow-up care with their physician or healthcare provider as additional testing may be necessary.

All negative results are presumptive and confirmation with a molecular assay, if necessary for patient management, may be performed. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control measures such as isolating from others and wearing masks. Negative results should be considered in the context of an individual's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19.

Individuals who test negative and continue to experience COVID-like symptoms of fever, cough and/or shortness of breath may still have SARS-CoV-2 infection and should seek follow up care from 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 GenBody COVID-19 Ag Home Test is intended for non-prescription self-use and/or, as applicable, an adult lay user testing another person aged 2 years or older in a non-laboratory setting.
The GenBody COVID-19 Ag Home Test is only for use under the Food and Drug Administration's Emergency Use Authorization. This product has not been FDA cleared or approved.

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.

Frequently Asked Questions

WHAT IS THE DIFFERENCE BETWEEN A COVID-19 ANTIGEN TEST AND A MOLECULAR TEST?
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, such as the GenBody COVID-19 Ag Home 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.

WHAT IS SERIAL TESTING?
COVID-19 serial testing is when one person tests themselves multiple times for COVID-19 on a routine basis, such as every other day. By testing more frequently, you may detect COVID-19 more quickly and reduce spread of infection. For the serial testing procedure, please refer to the 'How to Use This Test' section. You may need to purchase additional tests to perform this serial (repeat) testing.

HOW ACCURATE IS THIS TEST?
Clinical studies have shown that antigen tests more accurately determine whether you are infected with the virus that causes COVID-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.genbodyhometest.com.

WHAT ARE THE KNOWN AND POTENTIAL RISKS AND BENEFITS OF THE TEST?
Potential risks include:
- Possible discomfort or other complications that can happen 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.

For more information on EUAs please visit: https://www.fda.gov/emergency-preparedness-andresponse/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization

WHAT IF I HAVE A POSITIVE TEST RESULT?
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.

WHAT IF I HAVE A NEGATIVE TEST RESULT?
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 48 hours since antigen tests are not as sensitive as molecular tests. If you do not have symptoms and received a negative result, you should test at least two more times with 48 hours in between tests for a total of three tests. If you have a negative result, it does not rule out SARS-CoV-2 infection; 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.

WHAT DOES AN INVALID TEST RESULT MEAN?
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.

IMPORTANT
Do not use this test as the only guide to manage your illness. Consult your healthcare provider if your symptoms persist or become more severe. Individuals should provide all results obtained with this product to their healthcare provider.

Warnings, Precautions, and Safety Information

1. Read all instructions carefully before performing the test. Failure to follow the instruction may result in inaccurate test results.
2. In the USA, this product has not been FDA cleared or approved, but has been authorized by FDA under an Emergency Use Authorization. This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens. The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.
3. **Serial testing should be performed in individuals with negative results at least twice over three days (with 48 hours between tests) for symptomatic individuals and three times over five days (with at least 48 hours between tests) for asymptomatic individuals. You may need to purchase additional tests to perform this serial (repeat) testing.**
4. If you have had symptoms longer than 5 days, you should consider testing at least three times over five days with at least 48 hours between tests.
5. Do not use on anyone under 2 years of age.
6. An anterior nasal swab sample can be self-collected by an individual age 14 years and older. Children aged 2 to 13 years of age should be tested by an adult.
7. Do not use kit past its expiration date.
8. Do not use if any of the test kit contents or packaging is damaged.
9. Test components are single use only and should be discarded after use. Do not re-use.
10. Once opened, the test device should be used within 60 minutes.
11. **Do not read test results before 15 minutes or after 20 minutes. Results read before 15 minutes or after 20 minutes may lead to a false positive, false negative, or invalid result.**
12. Wear a safety mask or other face covering when collecting a specimen from a child or another individual.
13. Do not use nasal sprays for at least 30 minutes before collecting a nasal sample.
14. Do not touch the swab tip at any time during the test process.
15. Do not use the test device if the desiccant included in the foil pouch has changed from yellow to green.
16. Swabs included in the kit are approved for use with the GenBody COVID-19 Ag Home Test. Do not use other swabs.
17. For additional information on safety, handling, please email or call Technical Support at ts@genbodyamerica.com or (888)-552-5204
18. **Keep testing kit and kit components away from children and pets before and after use. Avoid contact with your skin or eyes. Do not ingest any kit components. The reagent solution contains harmful chemicals (see table below). If the solution contacts your skin or eyes, 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 each Ingredient	Concentration
Sodium azide	H302+H312, Harmful if swallowed or in contact with skin	0.09%

19. For more information on EUAs please visit: https://www.fda.gov/emergency-preparedness-andresponse/mcm- legal -regulatory-and-policy-framework/emergency-use-authorization
20. For the most up to date information on COVID-19, please visit: www.cdc.gov/COVID19

Limitations

1. 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.
2. This device is only used for testing direct human anterior nasal swab specimens. Viral transport media (VTM) should not be used with this test.
3. Incorrect test results may occur if a specimen is incorrectly collected or handled.
4. The performance of the GenBody COVID-19 Ag 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.
5. This 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.
6. 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.
7. Failure to follow the Test Procedure may adversely affect test performance and/or invalidate the test result.
8. Positive test results do not rule out co-infections with other pathogens.
9. All COVID-19 antigen test negative results are presumptive and confirmation with a molecular assay may be necessary.
10. This test is read visually and has not been validated for use by those with impaired vision or color-impaired vision.
11. If the test is positive, then proteins from the virus that causes COVID-19 have been found in the sample and you likely have COVID-19.
12. The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between November 2021 - September 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.

INTERNATIONAL SYMBOL USAGE
You may see one or more of these symbols on the labeling/packaging of this product.

Use-by date	Batch code	*In vitro* diagnostic device	Catalogue number	Consult instructions for use
Manufacturer	Contains sufficient for <n> tests	Temperature limit	Do not re-use	Test Device

For Technical Help, please contact:
Technical Support (US)
Tel: (888) 552-5204
Email: ts@genbodyamerica.com
Web: www.genbodyhometest.com

GenBody Inc.
CHANGE AND INNOVATION

Manufacturer	US Distributor / US Agent
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 Website: http://www.genbody.co.kr	Kwell Laboratories, LLC 3420 De Forest Circle Jurupa Valley, CA 91752 USA Tel: (949) 561-0664 Email: inquire@kwellabs.com Website: www.kwellabs.com

REF COVAGHT2-U-01, COVAGHT2-U-02, COVAGHT2-U-05, COVAGHT2-U-25.

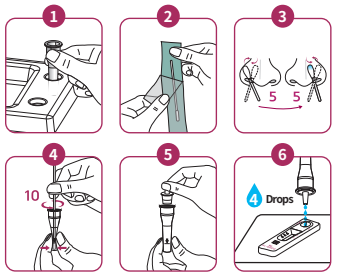
Doc. No.: I-164-EN-R0-202302-US

1 test kit box
122 x 83 x 30 mm

1 Test

GenBody
COVID-19 Ag Home Test

HOW TO USE



Questions?
Go to
www.genbodyhometest.com
or call (888) 552-5204
Email:
ts@genbodyamerica.com

The GenBody COVID-19 Ag Home Test is lateral flow immunoassay that uses antibodies to detect nucleocapsid protein from SARS-CoV-2. The GenBody COVID-19 Ag Home Test is a non-prescription home test intended for the qualitative detection of SARS-CoV-2 in anterior nasal swab samples self collected from individuals aged 14 years or older or adult-collected from individuals aged 2 years or older. This test is authorized for individuals within the first 5 days symptom onset when tested at least twice over three days with at least 48 hours between tests, and for individuals without symptoms when tested at least three times over five days with at least 48 hours between tests.

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Barcode

Manufactured by
GenBody Inc.
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31077, Republic of Korea
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US Distributor
Kwell Laboratories
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Jurupa Valley, CA 91752 USA
Tel: (949) 561-1664

Store between 35.6-86°F (2~30°C) until use
www.genbodyhometest.com

Rev.0

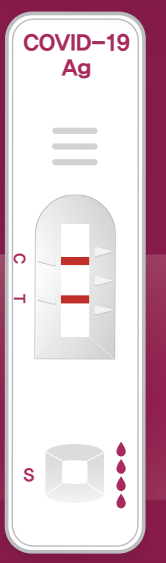
Warning

In the USA, this product has not been FDA cleared or approved, but has been authorized by FDA under an Emergency Use Authorization. This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens. The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

GenBody
COVID-19 Antigen Home Test

1 Test

GenBody
COVID-19 Antigen Home Test



EASY
Comfortable nasal swab

FAST
Results in 15 min

Contents

- 1 Test Device
- 1 Extraction Tube
- 1 Filter Tip
- 1 Nasal Swab
- 1 Instruction Sheet
- Needed but not provided: Timer, Tissue

IVD OTC 1 35.6°F 86°F

- Determining a negative result requires multiple tests. you may need to purchase additional tests to perform serial (repeat) testing. This test is more likely to give you a false negative result when you have COVID-19 than a lab-based molecular test.
- For Emergency Use Authorization (EUA) only
- For in vitro diagnostic use
- For the most current expiration dates of this test, please refer to: https://www.fda.gov/covid-tests.

LOT REF COVAGHT2-U-01

GenBody
COVID-19 Antigen Home Test

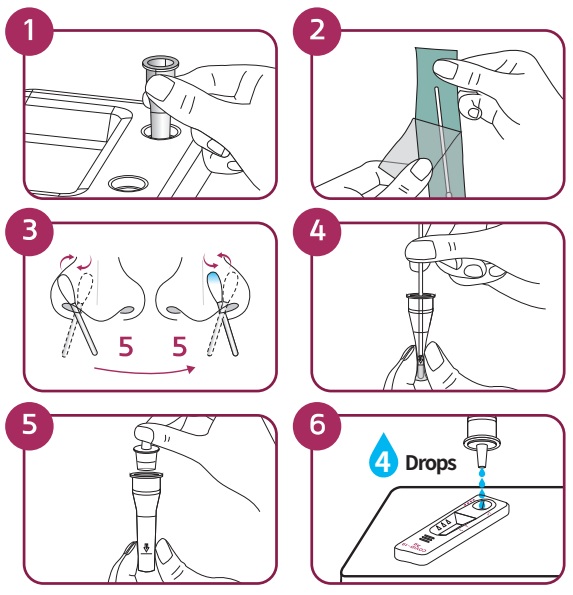
B-164(01)-EN-202302-US

2 test kit box
156.4 x 93 x 43.8 mm

GenBody
COVID-19 Ag Home Test

2 Tests

HOW TO USE



Warning

In the USA, this product has not been FDA cleared or approved, but has been authorized by FDA under an Emergency Use Authorization. This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens. The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

Store between 35.6-86°F (2~30°C) until use
www.genbodyhometest.com

Rev.0

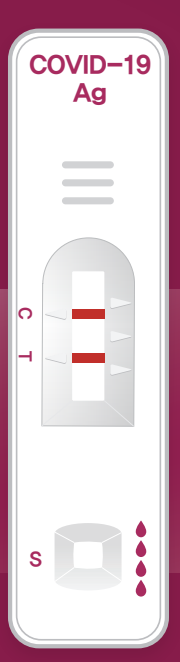
Manufactured by
GenBody Inc.
3-18, Eopseong 2-gil, Seobuk-gu Cheonan-si, Chungcheongnam-do 31077, Republic of Korea Tel: +82-41-523-8993
US Distributor Kwell Laboratories
3420 De Forest Circle Jurupa Valley, CA 91752 USA Tel: (949) 561-1664

The GenBody COVID-19 Ag Home Test is lateral flow immunoassay that uses antibodies to detect nucleocapsid protein from SARS-CoV-2.

The GenBody COVID-19 Ag Home Test is a non-prescription home test intended for the qualitative detection of SARS-CoV-2 in anterior nasal swab samples self collected from individuals aged 14 years or older or adult -collected from individuals aged 2 years or older . This test is authorized for individuals within the first 5 days symptom onset when tested at least twice over three days with at least 48 hours between tests, and for individuals without symptoms when tested at least three times over five days with at least 48 hours between tests.

GenBody
COVID-19 Antigen Home Test

2 Tests



EASY
Comfortable nasal swab

FAST
Results in 15 min

Contents

- 2 Test Device
- 2 Extraction Tube
- 2 Filter Tip
- 2 Nasal Swab
- 2 Instruction Sheet
- Needed but not provided: Timer, Tissue

IVD OTC Σ2 35.6°F 86°F

GenBody
COVID-19 Antigen Home Test

Questions?
Go to www.genbodyhometest.com
or call (888) 552-5204
Email: ts@genbodyamerica.com

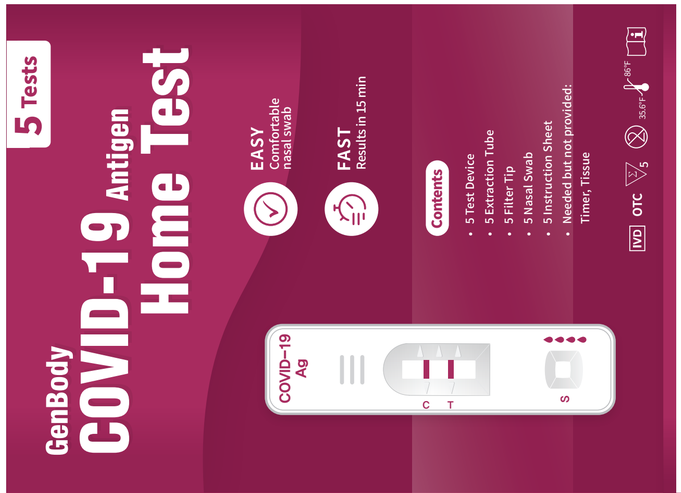
REF COVAGHT2-U-02
LOT

- Determining a negative result requires multiple tests. you may need to purchase additional tests to perform serial (repeat) testing. This test is more likely to give you a false negative result when you have COVID-19 than a lab-based molecular test.
- For Emergency Use Authorization (EUA) only
- For in vitro diagnostic use
- For the most current expiration dates of this test, please refer to: https://www.fda.gov/covid-tests.

Blank for UDI barcode

B-164(02)-EN-202302-US

5 test kit box
170 x 124 x 61 mm



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GenBody
COVID-19 Ag Home Test

Rev.0

REF COVAGHT2-U-05

LOT

Blank for UDI barcode

HOW TO USE

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www.genbodyhometest.com

Warning

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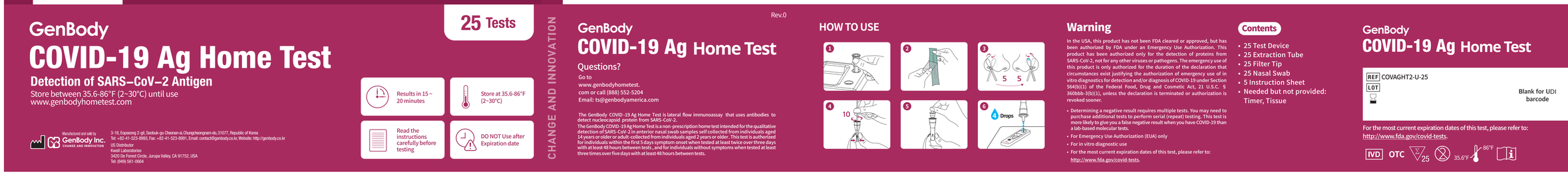
- For in vitro diagnostic use
- For the most current expiration dates of this test, please refer to: http://www.fda.gov/covid-tests.

B-164(05)-EN-202302-US

25 test kit box
300 x 125 x 90 mm



B-164(25)-EN-202302-US