GenBody Inc.
CHANGE AND INNOVATION

For use under *Emergency Use Authorization* Only
For *in vitro diagnostic* Use

GenBody COVID-19 Ag Home Test

Rapid Diagnostic Test for the Detection of SARS-CoV-2 Antigen

Healthcare Provider Instructions for Use (IFU)

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1. 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 as 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.

2. EXPLANATION OF THE TEST

COVID-19 (short for 'Coronavirus Disease 2019') is a disease first recognized in 2019 that is caused by a type of novel coronavirus called SARS-CoV-2. Due to its rapid spread, the World Health Organization (WHO) recognized the disease as a global pandemic on March 11, 2020. Individuals infected with SARS-CoV-2 may have a range of symptoms from asymptomatic infection to severe respiratory illness and even death. The virus is spread primarily from person to person through respiratory particles, even by individuals without symptoms.

The GenBody COVID-19 Ag Home Test is a rapid, qualitative lateral flow immunochromatographic assay for the determination of the presence of SARS-CoV-2 antigens in direct human anterior nasal (nares) swab specimens. The test strip in each device contains mouse monoclonal antibodies to the nucleocapsid protein (NP) of SARS-CoV-2. When the sample contains SARS-CoV-2 antigens, anti-SARS-CoV-2 monoclonal antibodies that are coupled with colloidal gold bind to SARS-CoV-2 antigens in the sample to form an antigen-antibody complex. This complex is then captured by anti-SARS-CoV-2 monoclonal antibodies immobilized on the Test line, and a visible line appears on the membrane, while unbound dye complexes continue to migrate beyond the test line area. Unbound protein-dye complexes are later captured at the Control line. Formation of the Control line serves as an internal control. If the Control line does not appear within the designated incubation time (i.e., 15 - 20 minutes), the result is invalid and the test should be repeated with a new sample. This test does not use biotin-streptavidin/avidin chemistry in any of the steps for coupling reagents. The GenBody COVID-19 Ag Home Test is validated for use from direct specimens testing without transport media.

3. MATERIALS PROVIDED

Kit Components	Quantity			
	1 Test Kit	2 Tests Kit	5 Tests Kit	25 Tests Kit
Catalog No.	COVAGHT2-U-01	COVAGHT2-U-02	COVAGHT2-U-05	COVAGHT2-U-25
Test Device	1 ea/box	2 ea/box	5 ea/box	25 ea/box
Extraction Buffer (0.4 mL/vial)	1 ea/box	2 ea/box	5 ea/box	25 ea/box
Filter Cap	1 ea/box	2 ea/box	5 ea/box	25 ea/box
Nasal Swab	1 ea/box	2 ea/box	5 ea/box	25 ea/box
Tube Holder	1 ea/box User foldable paper tray	1 ea/box Plastic tray	1 ea/box User foldable paper tray	5 ea/box User foldable paper tray
QRI/QRG/IFU	1 ea / box	1 ea / box	1 ea / box	5 ea/box

4. MATERIALS REQUIRED BUT NOT PROVIDED

- Timer
- Tissue

5. QUALITY CONTROL

Each GenBody COVID-19 Ag Home Test Device has a built-in internal procedural control. The reddish-purple line appearing at the "C" position is an internal procedural control. This procedural control line indicates that sufficient flow has occurred. A distinct reddish-purple Control line should always appear if the test has been performed correctly. If the Control line does not appear, the test result is invalid and a new test should be performed using a new sample and new test kit.

6. TEST PROCEDURES

Carefully read the instructions before performing the test. Failure to follow the instructions may result in inaccurate test results.

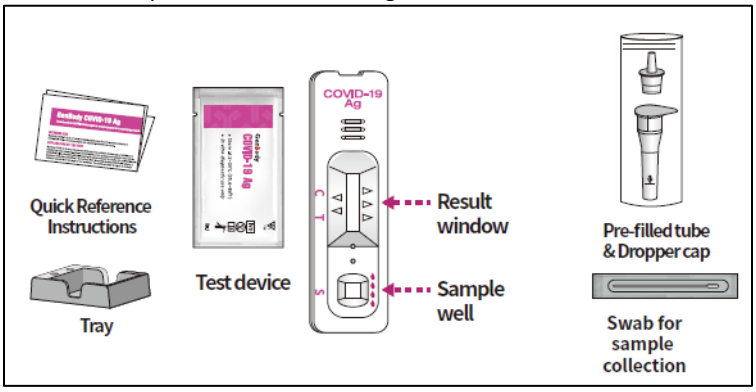
Procedural Notes

- Allow Test Devices, reagents, specimens, and/or controls to equilibrate to room temperature (15~30°C) prior to testing.
- Check expiration date on the back of the device pouch. Do not use an expired test.
- For the most current expiration dates of this test, please refer to, https://www.fda.gov/covid-tests
- Do not open the foil pouch until one is ready to perform the test.
- Using the enclosed tube holder is optional. When testing with the holder, please beware of buffer spillage.

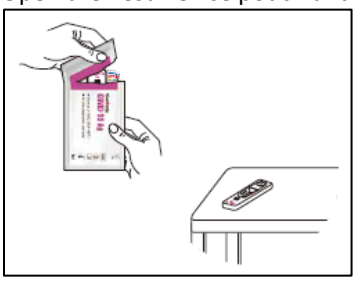
1) Test Preparation

a. Wash hands with soap or hand sanitizer and dry thoroughly.

b. Check all components before testing.



c. Open the Test Device pouch and lay the test device on a flat surface.



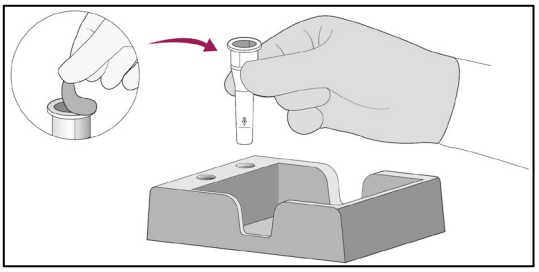
Note: Do not touch the result window or the sample well of the test device.

2) Sample Collection

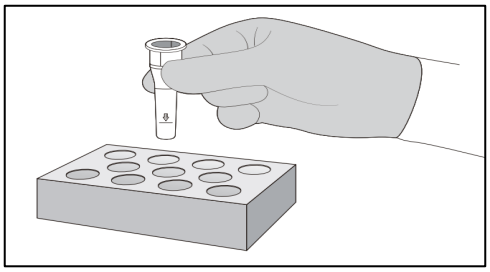
a. Peel off the foil cover from the pre-filled extraction buffer tube.

b. Insert the tube upright into the tray hole.

Catalog# COVAGHT2-U-02



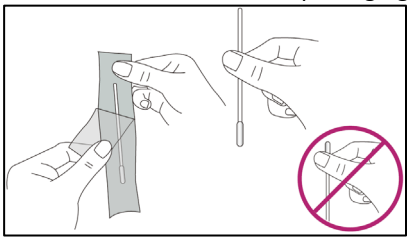
Catalog# COVAGHT2-U-01, -05, -25



Note #1: The type of the tray differs depending on the product catalog.
Note #2: Avoid exposure of your skin, eyes, nose or mouth to the solution in the tube.

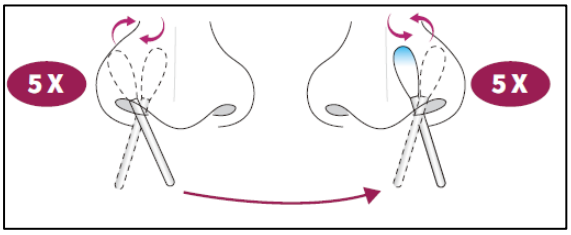
c. Blow nose thoroughly to clear the nasal passage.

d. Remove the swab from the packaging.



Note:
Do not touch swab head or lay the swab on any surface.

e. Collect the nasal swab sample



Note #1: For test accuracy, make sure to collect sample from both nostrils.
Note #2: A false negative result may occur if the nasal swab specimen is not properly collected.
Note #3: Wear a face mask if swabbing others.
Note #4: DO NOT insert the swab any deeper if you feel resistance or pain.

1) Self-collection

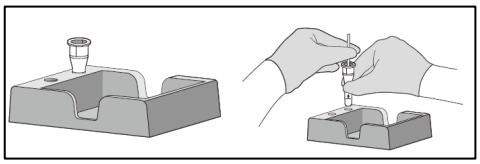
- A nasal swab sample can be self-collected by an individual aged 14 years and older.
- Insert the swab about a half inch deep into the nostril and slowly rub along the inside wall five times for 15 seconds with medium pressure. Using the same swab, repeat the process in the other nostril.

2) Child specimen collection
- 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. Using the same swab, repeat the process in the other nostril.

3) Test Procedure

a. After collecting the sample with the swab, insert the swab into the pre-filled tube

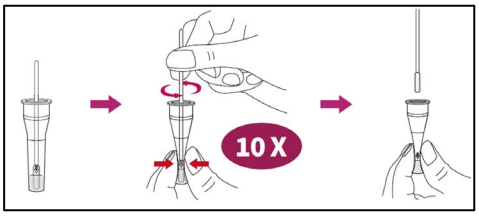
b. Using both hands, carefully remove the tube and swab together.



c. 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 twired at least 10 times)

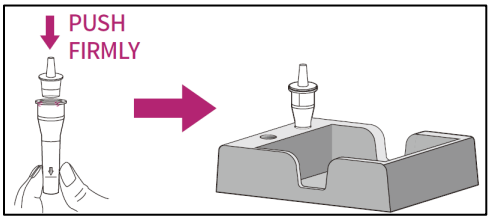
Note: Inadequate sample extraction can result in incorrect results.

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

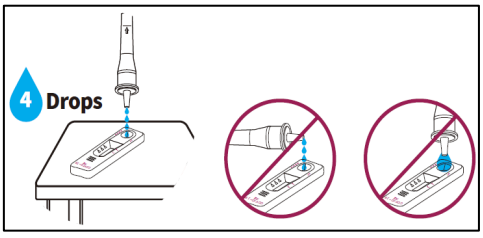


Note:
False negative results can occur if the specimen is not properly mixed or too vigorously mixed.

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

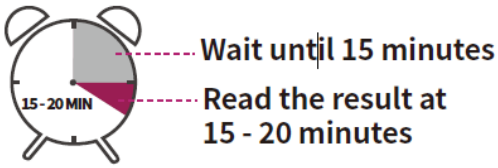


f. Invert the tube and hold the sample vertically above the sample well. Carefully squeeze 4 drops of the solution into the sample well of the device.



Note #1:
Adding other than recommended number of drops may result in incorrect results.
Note #2:
Do not touch the result window or the sample well of the test device.
Note #3:
Do not add sample to the rectangular result window.

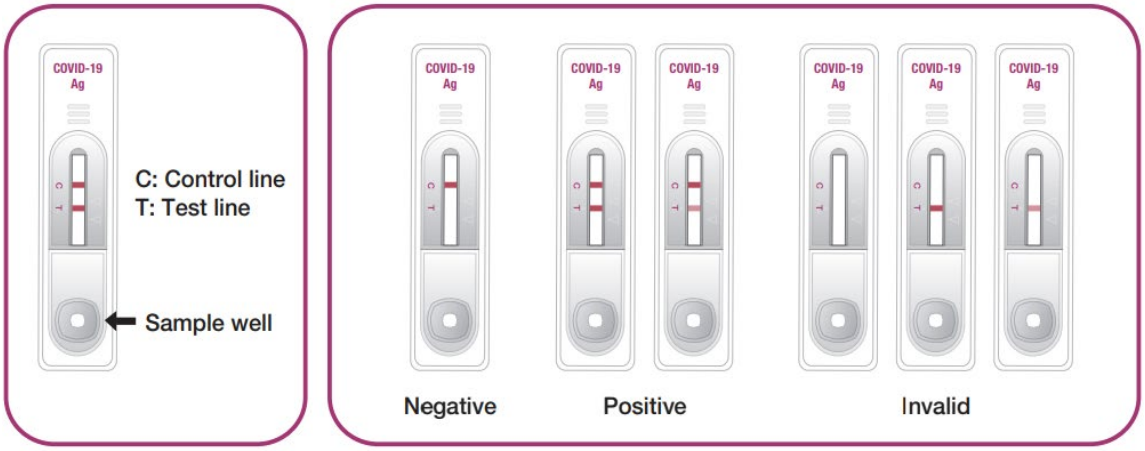
g. Wait 15 minutes and read the result. Do not read the result after 20 minutes. Inaccurate results may occur if the test result is read before 15 minutes or after 20 minutes.



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

7. INTERPRETATION OF THE RESULTS

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.



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.

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 the individual has symptoms on the first day of testing.**
- **Test 2 more times at least 48 hours apart if the individual does 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 the sample. A negative result does not rule out COVID-19. There is a higher chance of false negative results with antigen tests compared to laboratory-based tests such as PCR tests. If the test is negative but COVID-19-like symptoms, e.g., fever, cough, and/or shortness of breath continue, follow up testing for SARS-CoV-2 with a molecular test or testing for other respiratory disease should be considered. If applicable, seek follow up care with the primary 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.

COVID-19 Positive Result	**If the Control (C) line and the Test (T) line are visible, the test is positive. Any faint visible reddish-purple line Test (T) line with Control (C) line should be read as positive.**

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

A positive test result means that the virus that causes COVID-19 was detected in the sample, and it is very likely the individual has COVID-19 and is contagious. Please contact the patient's doctor/primary care physician (if applicable) 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 GenBody COVID-19 Ag Home 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.

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

8. STORAGE AND STABILITY

- GenBody COVID-19 Ag Home Test should be stored between 35.6 to 86 °F (2 to 30 °C). Ensure all test components are at room temperature before use.
- Kit components in the GenBody COVID-19 Ag Home Test are stable until the expiration date printed on the external packaging. For more information on expiration dating for COVID-19 antigen tests, please refer to http://www.fda.gov/covid-tests.
- Due to potential for test failure at high temperature and high humidity, the Test Device must remain in the sealed foil pouch until use.
- For more information on expiration dating for COVID-19 antigen tests, please refer to http://www.fda.gov/covid-tests. DO NOT FREEZE. Once the pouch has been opened, the test device should be used within 60 minutes. Use beyond one hour may not produce accurate results.

9. 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. 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. 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: https://www.cdc.gov/COVID19

10. 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 the individual likely has 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.

11. PERFORMANCE CHARACTERISTICS

a. Analytical Sensitivity: Limit of Detection (LoD)

The Limit of Detection (LoD) of the GenBody COVID-19 Ag Home Test was determined using serial dilutions of the heat-inactivated SARS-CoV-2 (USA-WA1/2020). Testing sample was prepared by spiking the strain into the pooled human nasopharyngeal swab matrix obtained from healthy volunteers confirmed negative by RT-PCR. All tests at each dilution were performed by adding 50 µL sample to a swab and then testing with the GenBody COVID-19 Ag Home Test Devices according to the test procedure. The initially determined LoD by two-fold serial dilution was confirmed by testing in 20 replicates.

The confirmed LoD for the GenBody COVID-19 Ag Home Test was 1.11×10^2 $TCID_{50}$/mL. Based upon the testing procedure for this study the LoD of 1.11×10^2 $TCID_{50}$/mL equates to 5.55 $TCID_{50}$/swab.

b. NIH/RADx Variant Testing (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, GenBody COVID-19 Ag Home Test detected 100% of live virus Omicron samples at a Ct-value of 25.0 (n=25). Testing was also compared to additional EUA authorized OTC antigen tests (Assay #1 and Assay #2). Omicron dilutions at lower viral concentrations (Ct values greater than 27.3) were not detected by the GenBody COVID-19 Ag Home Test in this study. The data for the omicron testing is presented in the table below.

Omicron Live Pool 1 Samples	Average N2 Ct (n=9)	Assay #1 Percent Positive (n=5)	Assay #2 Percent Positive (n=5)	GenBody COVID-19 Ag Home Test Percent Positive (n=25)
Dilution 1	19.9	100	100	100 (25/25)
Dilution 2	21	100	100	100 (25/25)
Dilution 3	22.3	100	100	100 (25/25)
Dilution 4	23.4	100	100	100 (25/25)
Dilution 5	25	100	100	100 (25/25)
Dilution 6	26.6	100	100	68 (17/25)
Dilution 7	27.3	0	100	8 (2/25)
Dilution 8	28.7	0	100	0
Dilution 9	30.1	0	0	0
Dilution 10	31	0	0	0
Dilution 11	32.1	0	0	0

c. Endogenous Interfering Substances

The interference study was performed for the 30 potentially interfering substances that may be found in the upper respiratory tract or household items. The positive (2x LoD SARS-CoV-2) and negative samples were tested with the addition of potentially interfering substances. The performance of GenBody COVID-19 Ag Home Test was not affected by any of the potentially interfering substances listed in the table below at the concentrations tested.

Substance	Concentration
Whole blood	5%
NasoGEL (NeilMed)	5% v/v
Phenylephrine (Nasal Drop)	10% v/v
Acetylsalicylic acid	20 mg/ml
Beclomethasone	0.5 mg/ml
Benzocaine (Vicks)	5%
Flunisolide	3 mg/ml
Mucin (Bovine submaxillary gland)	0.5%
Menthol	10 mg/ ml
Oxymetazoline (Afrin)	15% v/v
Tobramycin	40 mg/ml
Hand soap (Lauric acid)	1% v/v
Hand sanitizer (Benzalkonium chloride)	2% v/v
Bleach (Sodium hypochlorite)	1% v/v
Shampoo (Sodium laureth sulfate)	1% v/v
Hand Lotion	1% v/v

Substance	Concentration
Zanamivir	3.3 mg/ml
Oseltamivir phosphate (Tamiflu)	12 mg/mL
Cromolyn (Nasal Spray)	40 mg/ ml
Homeopathic (Alkalol)	5% v/v
Zicam Cold Remedy	5% v/v
Mucous	35% v/v
Guaiacol glyceryl ether	20 mg/ml
Chloraseptic (Menthol/Benzocaine)	1.5 mg/mL
Chloraseptic spray (phenol)	15% v/v
Mupirocin	10 mg/mL
Fluticasone Propionate	5% v/v
Dish-washing liquid (Sodium lauryl sulfate, Citric acid)	1% v/v
Hand gel (Ethyl alcohol)	1.61% v/v
Fabric softener (Benzyl salicylate)	1% v/v
Biotin	3.5 ug /mL

d. Analytical Specificity: Cross-reactivity and Microbial interference

Cross-reactivity and interference studies were performed for related pathogens, high prevalence disease agents, and normal or pathogenic flora that are reasonably likely to be encountered in the clinical specimen of the nasal cavity. Each organism and virus (15 bacteria and 29 viruses) was tested in both the absence and presence of inactivated SARS-CoV-2 (SARS-CoV-2 isolate USA-WA1/2020) at the 2x LoD. All testing samples were prepared in the negative clinical nasopharyngeal matrix. No cross reactivity or interference was observed at the concentrations tested as shown in the table below.

Microorganism	Concentration
Adenovirus (C1 Ad. 71)	1.41 x 10^6 $TCID_{50}$/mL
Enterovirus D68	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)	1.41 x 10^6 $TCID_{50}$/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
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 10^6 $TCID_{50}$/mL
SARS-coronavirus (in PBS)	1 x 10^8 pfu /mL
SARS-coronavirus (Vero E6 Cell DMEM)	1 x 10^8 pfu /mL
Respiratory syncytial virus - Type A	3.80 x 10^6 $TCID_{50}$/mL
Respiratory syncytial virus - Type B	1 x 10^7 $TCID_{50}$/ mL

Microorganism		Concentration
Hepatitis B Virus (Performance panel, Seracare, 0805-0362, Batch#10387873)	DNA genotype-A	5.5 x 10^7 IU/ mL
	DNA genotype-B	4.2 x 10^5 IU/ mL
	DNA genotype-C	1.0 x 10^8 IU/ mL
	DNA genotype-D	3.2 x 10^3 IU/ mL
	DNA genotype-E	3.5 x 10^3 IU/ mL
	DNA genotype-F	1.5 x 10^5 IU/ mL
	DNA genotype-H	3.0 x 10^2 IU/ mL
Herpes Simplex Virus-1		1 x 10^6 $TCID_{50}$/ mL
Herpes Simplex Virus-2		1 x 10^6 U/ mL
Hepatitis C Virus		1 x 10^6 $TCID_{50}$/ 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
Pseudomonas aeruginosa		3.44 x 10^9 CFU/mL

Rhinovirus Type 1A	1 x $10^{6.58}$ $TCID_{50}$/mL
Rhinovirus Type 14	9.8 x 10^7 pfu/ mL
Rhinovirus Type 42	4.2 x 10^5 pfu / mL
Cytomegalovirus	1 x 10^7 U/ mL
Epstein-Barr Virus	2.70 x 10^8 cp/ mL
Varicella Zoster Virus	4 x 10^8 cp/ mL
Parvovirus B19	8 x 10^8 IU/ mL
Human Immunodeficiency Virus – 1	4 x 10^9 IU/ mL
Human Immunodeficiency Virus – 2	5.6 x 10^7 U/ mL

Staphylococcus epidermidis	9.27 x 10^9 CFU/mL
Staphylococcus aureus	8.5 x 10^6 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
Escherichia coli	1.3 x 10^8 CFU/ mL
Bordetella pertussis	1.13 x 10^{10} CFU/mL
Pooled human nasal wash – representative of normal respiratory microbial flora	100%

To estimate the likelihood of cross-reactivity with SARS-CoV-2 of organisms that were not available for wet testing, *in-silico* analysis using the Basic Local Alignment Search Tool (BLAST) managed by the National Center for Biotechnology Information (NCBI) was used to assess the degree of protein sequence homology. HKU1 nucleocapsid phosphoproteins, *Mycobacterium tuberculosis*, and *Pneumocystis jirovecii* (PJP) were analyzed and results are below.

- The homology between SARS-CoV-2 nucleocapsid protein and human coronavirus HKU1 nucleocapsid phosphoproteins is relatively low, at 36.7% across 82% of sequences, but cross-reactivity cannot be ruled out.

- The homology between SARS-CoV-2 nucleocapsid protein and *Pneumocystis jirovecii* (PJP) total protein is relatively low, at 22.0% across 4% of sequences, but cross-reactivity cannot be ruled out.

- No homologous protein sequence was found as a result of *in-silico* analysis with *Mycobacterium tuberculosis* total protein and SARS-CoV-2 nucleocapsid protein. Despite there being little homology observed, the cross-reactivity of GenBody COVID-19 Ag Home Test against *Mycobacterium tuberculosis* cannot be ruled out.

e. High-dose hook effect

The GenBody COVID-19 Ag Home Test was tested up to 1.15 x 10^7 $TCID_{50}$/mL of heat-inactivated SARS-CoV-2 (USA-WA1/2020) and no high-dose hook effect was observed.

12. CLINICAL EVALUATION

12.1. Clinical Performance

A combined prospective clinical study was completed for clinical validation of the GenBody COVID-19 Ag Home Test for detection of SARS-CoV-2 in subject-collected and tested anterior nasal (AN) swab samples. Subjects were enrolled in regions of high COVID-19 incidence at ten (10) geographically diverse clinical sites within the United States. The clinical study evaluated the investigational test's performance in symptomatic individuals suspected of COVID-19 infection against the results generated by highly sensitive molecular EUA SARS-CoV-2 comparators.

The study enrolled 629 subjects two (2) years of age or older presenting with symptoms associated with COVID-19, within five (5) days of symptom onset who were currently experiencing symptoms. Each enrolled subject either self-collected their sample from the anterior nares (swabbing both nostrils) or had their sample collected from him/her by another individual (who swabbed both nostrils) and performed the self-test according to the test Quick Reference Instructions (QRI, or layperson instructions for use). Study personnel then collected a sample from the subjects, which was then shipped to a reference laboratory for testing with the EUA comparator assays(s).

The study included a total of 104 evaluable positive samples and 495 evaluable negative samples (defined as positive or negative according to comparator assay(s)). Analysis of the Ct values of the comparator RT-PCR assay(s) confirmed that 25 (24%) study subjects who were positive according to comparator assay(s) had low viral loads (high Ct values). This may be associated with the Omicron variant since the low positive percentage in this study is higher than that observed in prior clinical studies for previously authorized COVID-19 rapid antigen tests. Antigen test performance decreases as the percent of low positives increases since the molecular comparator method is more sensitive than the candidate antigen test. Therefore, to be consistent with previous studies, the analysis for the primary performance calculation was conducted to reflect study populations with samples containing between 10% to 20% low virus concentrations (controlled analysis). The Percent Positive Agreement (PPA) for the various cohorts are shown in the table below. At 10% low positives, the PPA was 87.5% and the NPA was 99.2% with 95% confidence interval bounds of 79.0%-92.9% for PPA and 97.9%-99.7% for NPA respectively. This was the basis of the authorization. At 20% low positives, the PPA was 79.8% with 95% confidence interval bounds of 70.8%- 86.5%.

Controlled Analysis of GenBody COVID-19 Ag Home Test low positive results vs molecular comparator results						
Measure	**Overall**	**10% Low Positive**	**12.5% Low Positive**	**15% Low Positive**	**17.5% Low Positive**	**20% Low Positive**
High Positive	79	79	79	79	79	79
Low Positive	25	9	12	14	17	20
Total Comparator Positive For PPA	104	88	91	93	96	99
True Positive by Device	81	77	77	77	77	79
PPA	77.9%	87.5%	84.6%	82.8%	80.2%	79.8%
(95% CI)	(69.0%-84.8%)	(79.0%-92.9%)	(75.8%-90.6%)	(73.9%-89.1%)	(71.1%-86.9%)	(70.8%-86.5%)
NPA	99.2%	99.2%	99.2%	99.2%	99.2%	99.2%

When all study participants are included, the PPA is 77.9% and the NPA is 99.2% with the 95% confidence interval bounds of 69.0% to 84.8% for the PPA and 97.9% to 99.7% for the NPA, respectively.

Clinical Performance in Subjects on Different Symptomatic Days

Days of COVID-19 Symptoms	Number of Subject Samples Tested	Investigational Positives	Comparator Positives	% Positivity Rate (by Comparator)	PPA (%)
Day 0	71	8	10	14.1%	80.0%
Day 1	160	18*	24	15.0%	75.0%
Day 2	141	18*	23	16.3%	78.3%
Day 3	121	16*	21	17.4%	76.2%
Day 4	67	10	14	20.9%	71.4%
Day 5	39	11	12	30.8%	91.7%
Total	599	81	104	17.4%	77.9%

*4 samples were false positive by the comparator and were not included in the table

Positivity Rate by Age

	Number of Specimens	Number of Positives by Comparator	% Positivity Rate
<14 years of age	74	15	20.3%
14-24 years of age	64	6	9.4%
>24-64 years of age	389	72	18.5%
≥65 years of age	72	11	15.3%
Total	599	104	17.4%

12.2. Serial Testing

A prospective clinical study was conducted between January 2021 and May 2022 as a component of the Rapid Acceleration of Diagnostics (RADx) initiative from the National Institutes of Health (NIH). A total of 7,361 individuals were enrolled via a decentralized clinical study design, with a broad geographical representation of the United States. Per inclusion criteria, all individuals were asymptomatic upon enrollment in the study and at least 14 days prior to it and did not have a SARS-CoV-2 infection in the three months prior to enrollment. Participants were assigned to one of three EUA authorized SARS-CoV-2 OTC rapid antigen tests to conduct serial testing (every 48 hours) for 15 days. If an antigen test was positive, the serial-antigen testing result is considered positive.

At each rapid antigen testing time point, study subjects also collected a nasal swab for comparator testing using a home collection kit (using a 15-minute normalization window between swabs). SARS-CoV-2 infection status was determined by a composite comparator method on the day of the first antigen test, using at least two highly sensitive EUA RT-PCRs. If results of the first two molecular 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 Table below.

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	Asymptomatic on First Day of Testing			Symptomatic on First Day of Testing		
	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 (50.0%)	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 (75.0%)	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.
2 Tests: two (2) tests performed an average of 48 hours apart. The first test performed on the indicated day and the second test performed 48 hours later.
3 Tests: three (3) tests performance an average of 48 hours apart. The first test performed on the indicated day, the second test performed 48 hours later, and a final test performed 48 hours after the second test.

13. TECHNICAL SUPPORT

For questions, or to report a problem, please call Technical Support at (888) 552-5204
(Available Hours: Mon. to Fri.: 9 a.m. – 5 p.m. PST) or ts@genbodyamerica.com.

Test system problems may also be reported to the FDA using the MedWatch reporting system
(phone: 1-800 FDA-1088; fax: 1-800 FDA-1078: or http://www.fda.gov/medwatch).

14. ORDERING AND CONTACT INFORMATION

Kwell Laboratories, LLC (US Distributor/US Agent)
Tel: (949) 561-0664
Email: inquire@kwelllabs.com

15. INTERNATIONAL SYMBOL USAGE

You may see one or more of these symbols on the labelling/packaging of this product:

	Use-by date	LOT	Batch Code	IVD	*In vitro* diagnostic device
REF	Catalog number		Consult instructions for use		Manufacturer
	Contains sufficient for <n> test		Temperature limit		Do not reuse
TEST	Test Device				

REF	**COVAGHT2-U-01** **COVAGHT2-U-02** **COVAGHT2-U-05** **COVAGHT2-U-25**	**[GenBody COVID-19 Ag Home Test]**

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