GenBody Inc.
CHANGE AND INNOVATION

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

GenBody COVID-19 Ag

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

Instructions for Use
(IFU)

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1. INTENDED USE

The GenBody COVID-19 Ag is an immunochromatographic rapid diagnostic test (RDT) intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in direct nasopharyngeal (NP) or anterior nasal (AN) swab specimens from individuals who are suspected of COVID-19 by their healthcare provider within the first six days of symptom onset when tested at least twice over three days with at least 48 hours between tests, and from 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. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform moderate, high, or waived complexity tests. This product is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance or Certificate of Accreditation.

Results are for the identification of SARS-CoV-2 nucleocapsid antigen. Antigen is generally detectable in nasopharyngeal (NP) or anterior nasal (AN) swab specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities.

All negative results are treated as presumptive and may be confirmed with a molecular assay, if necessary, for patient management. 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 a patient's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19.

The GenBody COVID-19 Ag is intended for use by medical professionals or operators trained in performing tests in point of care settings. The GenBody COVID-19 Ag is only for *in vitro* diagnostic use under the Food and Drug Administration's Emergency Use Authorization. This product has not been FDA cleared or approved.

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 test is a rapid, qualitative immunochromatographic assay for the determination of the presence of SARS-CoV-2 antigens in human nasopharyngeal or anterior nasal 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 Test Device and a new sample.

3. MATERIALS PROVIDED

Kit Component	Quantity	Description
GenBody COVID-19 Ag Test Device	Twenty-five (25) single use Test Devices	Individually pouched devices with a desiccant. Test Device contains one reactive test strip.
	The test strip contains a membrane coated with mouse anti-SARS-CoV-2 NP antibodies for the test line and mouse anti-Nus tag antibodies for the control line, and a conjugate pad impregnated with Mouse anti-SARS-CoV-2 NP antibodies and recombinant Nus tag antigens	
Extraction Solution (400 µL/test tube)	Twenty-five (25) single use tubes containing 400 µL of Extraction Solution	Pre-filled buffer with detergent and preservative (<0.1% sodium azide).
Dropper Tips	Twenty-five (25) single use dropper tips	Disposable Extraction Tube tips for dispensing the extracted sample
Sterilized Nasopharyngeal or Anterior Nasal Swabs	Twenty-five (25) single use specimen sampling swabs	Swab for nasopharyngeal or anterior nasal sample collection with a flexible/breakable handle
External Positive Control Swab	One (1) single use swab	Individually pouched swab coated with non-infectious recombinant SARS-CoV-2 protein antigen on the head
External Negative Control Swab	One (1) single use swab	Individually pouched swab coated with buffer on the head
Instructions for Use (IFU)	One (1)	Instructions for use
Quick Reference Instructions (QRI)	One (1)	Quick reference instructions
Tube Holder	One (1)	Foldable paper tray for holding extraction tubes

4. MATERIALS REQUIRED BUT NOT PROVIDED

- Timer
- Any necessary personal protective equipment including gloves

5. QUALITY CONTROL

Internal Quality Control

Each GenBody COVID-19 Ag 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, and the functional integrity of the test device has been maintained. 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.

External Quality Control

Good laboratory practice includes the use of external controls to ensure proper kit performance. Using the external controls provided in the kit, it is recommended that external control testing be performed with each new operator and before using a new lot or shipment of GenBody COVID-19 Ag kits to confirm the expected Quality Control (QC) results. The frequency of additional QC tests should be determined according to your laboratory's standard QC procedures and local, State and Federal regulations or accreditation requirements. Upon confirmation of the expected results, the kit is ready for use with patient specimens. The GenBody COVID-19 Ag kit contains two control swabs. Test the control swabs in the same manner as patient specimens. When the positive control is tested, reddish-purple lines appear at the C and T positions. When the negative control is tested, a reddish-purple line appears at the C position only. If external controls do not perform as expected, do not use the test results and contact Technical Support at (888) 552-5204 or ts@genbodyamerica.com.
The use of positive and negative controls from other commercial kits has not been established with the GenBody COVID-19 Ag test.

6. SPECIMEN COLLECTION AND STORAGE

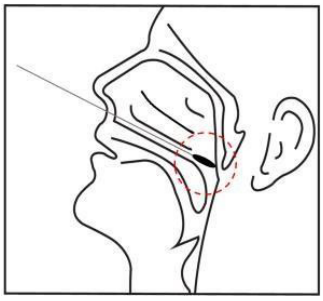
Swab Specimen Collection Procedure

Only the swab provided in the kit is to be used for swab specimen collection. If a deviated septum or blockage creates difficulty in obtaining the specimen from one nostril, use the same swab to obtain the specimen from the other nostril. Refer to the CDC Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons for Coronavirus Disease 2019 (COVID-19) (https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html).

Specimen Storage and Handling Procedure

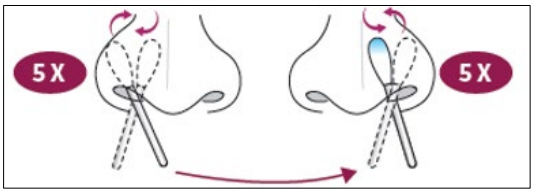
For the best performance, swab specimens collected from patients should be tested immediately after collection. The collected swab specimen can be tested for up to 60 minutes following specimen collection. If the specimen is extracted from the swab, the extracted specimen can be tested for up to 5 hours if stored between 2-30°C.

A. Nasopharyngeal Swab Sample Collection Procedure



1) Remove a nasopharyngeal swab from the pouch.
2) With the patient's head tilted backwards at 70 degrees, carefully insert the swab into the nostril that presents the most secretion under visual inspection.
3) Gently and slowly insert the swab through the nostril parallel to the palate (not upwards) until resistance is encountered or the distance is equivalent to that from the ear to the nostril of the patient, indicating contact with the nasopharynx.
4) Leave the swab in place for several seconds to absorb secretions.
5) Rotate the swab 3-5 times against the posterior nasopharynx.
6) Using gentle rotation, remove the swab from the nostril; insert into the Extraction Tube.
7) All specimens should be tested as soon as they are prepared.

B. Anterior Nasal Swab Sample Collection Procedure



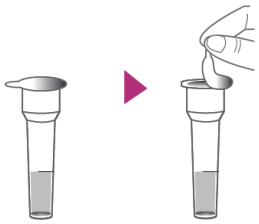
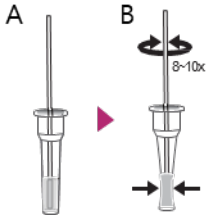
1) Remove a nasal anterior swab from the pouch.
2) Insert the swab ½ to ¾ of an inch into the RIGHT nostril.
3) In a circular motion, rub the swab around the entire wall of the nostril with some pressure. This should be performed for at least 5 circles and 15 seconds.
4) Withdraw the swab and repeat the same process on the LEFT nostril.
5) Withdraw the swab from the second nostril. Immediately after BOTH nostrils have been swabbed, place the swab into the extraction tube.
6) All specimens should be tested as soon as they are prepared.

7. TEST PROCEDURES

Procedural Notes

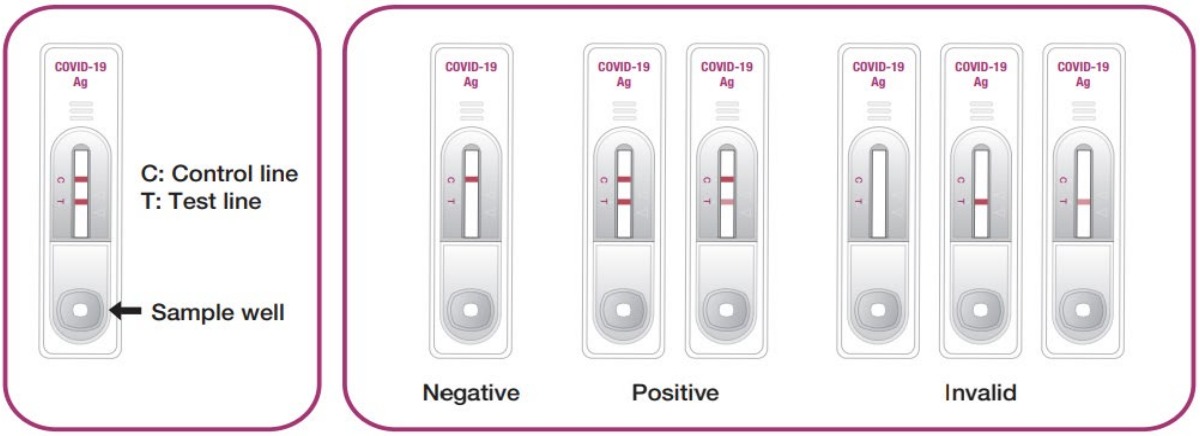
- Allow Test Devices, reagents, specimens, and/or controls to equilibrate to room temperature (15~30°C) prior to testing.
- Do not open the foil pouch until one is ready to perform the test.
- Label the device with the patient identification or control to be tested.
- Place Test Device on a level surface.
- Used specimens, swab, tube, and Test Device should be treated as biohazardous waste.
- Using the enclosed tube holder is optional. When testing with the holder, please beware of buffer spillage.

Specimen Swab Test Procedure

Step 1		Peel off the foil cover from the pre-filled tube. Be careful to avoid spillage of the extraction solution.
Step 2		A. Insert the collected specimen swab into the Extraction Solution. B. Mix by squeezing the tube and simultaneously twirling the swab 8 – 10 times. Remove the swab from the Extraction Tube while squeezing the swab against the side of the tube to extract the solution. Caution: **Inadequate sample extraction can result in incorrect results.**

Step 3		Place the Dropper Tip on the Extraction Tube.
Step 4		Add 4 drops (~100 µL) of the solution to the center of the sample well of the Test Device.
Step 5		Read the test result at 15-20 minutes. Test results should not be read after 20 minutes. Caution: **False positive or false negative results can occur if test device is read before 15 minutes or after 20 minutes**

8. INTERPRETATION OF THE RESULTS



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 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.**

9. STORAGE AND STABILITY

- GenBody COVID-19 Ag kit should be stored between 2 to 30 °C (35.6 to 86 °F).
- Kit components in the GenBody COVID-19 Ag kit are stable until the expiration date printed on the label.
- The Test Device must remain in the sealed foil pouch until use.

10. WARNINGS & PRECAUTIONS AND SAFETY INFORMATION

1) For *in vitro* diagnostic use only.
2) For prescription use only.
3) Read all instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate test results.
4) In the USA, this product has not been FDA cleared or approved, but has been authorized by FDA under an Emergency Use Authorization for use by laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform moderate, high or waived complexity tests. This product is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation. 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.
5) Federal Law restricts this device to sale by or on the order of a licensed practitioner (US only).
6) Laboratories within the United States and its territories are required to report all results to the appropriate public health laboratories.
7) **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.**
8) If you have had symptoms longer than 6 days, you should consider testing at least three times over five days with at least 48 hours between tests.
9) Do not use on anyone under 2 years of age.
10) Do not use kit past its expiration date.
11) Do not store or test specimens in viral transport media, as it may result in false positive or false negative results.
12) Do not touch the swab tip.
13) Wear a safety mask or other face-covering when collecting a specimen from a child or another individual.
14) It is recommended that personal protection equipment and gloves (not provided) be worn when running each test and handling patient specimens.
15) The Extraction Solution in this kit contains a detergent and a preservative that will inactivate cells and virus particles. Samples eluted in this solution are not suitable for culture.
16) Test components are single use. Do not re-use.
17) Proper sample collection, storage and transport are essential for correct results. Specimens should be prepared in accordance with the instructions provided in the "Specimen Collection and Storage" section.
18) Excess blood or mucus on the swab specimen may interfere with test performance, potentially yielding an inaccurate result. Avoid touching any bleeding areas of the nasopharynx when collecting specimens.
19) Users should test specimens as quickly as possible after specimen collection.
20) Do not use if any of the test kit contents or packaging is damaged.
21) Exposure to humidity may decrease the stability of the reagents. The test should be performed immediately after removing the device from the foil pouch.
22) **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.**

23) Extraction Buffer volume below the recommended amount may interfere with test performance, potentially yielding an inaccurate result.
24) Inadequate or inappropriate sample extraction may yield false test results.
25) Discard the extraction solution if it is spilled before the sample extraction. A reduced volume of extraction solution may produce an inaccurate result.
26) Test devices and swabs should be used immediately upon opening; do not remove Test Devices from the pouch until just before use.
27) Once opened, the Test Device should be used within 1 hour.
28) Do not use the Test Device if the desiccant included in the foil pouch has changed from yellow to green.
29) To ensure delivery of adequate volume, hold the tube vertically and add drops slowly.
30) Dispose of used contents as biohazardous wastes in accordance with federal, state, and local requirements.
31) Test results must be evaluated in conjunction with other clinical data available to the licensed practitioner.
32) Do not use the kit components from different lots.
33) Swabs included in the kit are approved for use with the GenBody COVID-19 Ag test. Do not use other swabs.
34) Do not smoke, eat, or drink in areas in which specimens or kit reagents are handled.
35) **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%

36) For additional information on safety, handling, and disposal of the components within this kit, including the Safety Data Sheet (SDS), please email or call Technical Support at ts@genbodyamerica.com or (888)-552-5204.
37) For more information on EUAs please visit: https://www.fda.gov/emergency-preparedness-andresponse/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization
38) For the most up to date information on COVID-19, please visit: https://www.cdc.gov/COVID19

11. LIMITATIONS

1) This device is for professional *in vitro* diagnostic use only.
2) This device is only used for testing direct human nasopharyngeal or anterior nasal swab specimens. Viral transport media (VTM) should not be used with this test.
3) This test is not for use in at-home testing settings.
4) This test is read visually and has not been validated for use by those with impaired vision or color-impaired vision.
5) The amount of antigen in a sample may decrease as the duration of illness increases. Specimens collected after six days are more likely to be negative compared to RT-PCR.
6) A negative test result may occur if the level of antigen in a sample is below the detection limit of the test.
7) Incorrect test results may occur if a specimen is incorrectly collected or handled.
8) The performance of the GenBody COVID-19 Ag was evaluated using the procedures provided in these Instructions for Use (IFU) only. Modifications to these procedures may alter the performance of the test.
9) 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.
10) The intensity of the Control (C) line should not be compared to that of the Test (T) line for the interpretation of the test result.
11) Positive test results do not rule out co-infections with other pathogens.
12) All COVID-19 antigen test negative results are presumptive and confirmation with a molecular assay may be necessary.

13) 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.
14) 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.
15) Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.
16) Negative test results are not intended to rule in other non-SARS viral or bacterial infections.
17) The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between January 2021 to February 2021 (nasopharyngeal) and between April 2021 to July 2021 (anterior nasal). 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.
18) 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.

12. CONDITIONS OF AUTHORIZATION FOR LABORATORY

The GenBody COVID-19 Ag Letter of Authorization, along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for patients, and authorized labeling are available on the FDA website: (https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-antigen-diagnostic-tests-sars-cov-2)

However, to assist clinical laboratories using the GenBody COVID-19 Ag ("your product" in the conditions below), the relevant Conditions of Authorization are listed below:

A. Authorized laboratories* using your product must include, with test result reports, all Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.
B. Authorized laboratories using your product must use your product as outlined in the authorized labeling. Deviations from the authorized procedures -- including from the authorized instruments, authorized clinical specimen types, authorized control materials, other authorized ancillary reagents, and authorized materials required to use your product -- are not permitted.
C. Authorized laboratories that receive your product must notify the relevant public health authorities of their intent to run your product prior to initiating tests.
D. Authorized laboratories using your product must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
E. Authorized laboratories must collect information on the performance of your product and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and GenBody Inc. (via email: ts@genbodyamerica.com) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of your product of which they become aware.
F. All operators using your product must be appropriately trained in performing and interpreting the results of your product. Use appropriate personal protective equipment when handling this kit, and use your product in accordance with the labeling.
G. GenBody Inc. and authorized laboratories using your product must ensure that any records associated with this EUA are maintained until otherwise notified by the FDA. Such records will be made available to the FDA for inspection upon request.

*The letter of authorization refers to, "Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high, moderate or waived complexity tests. This product is authorized for use at the Point of Care (POC) i.e. in patient care settings operating under CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation" as "authorized laboratories."

13. PERFORMANCE CHARACTERISTICS

a. Analytical Sensitivity: Limit of Detection (LoD)

The Limit of Detection (LoD) of the GenBody COVID-19 Ag 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 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 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 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 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 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. High-dose hook effect

The GenBody COVID-19 Ag 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.

d. Endogenous Interfering Substances

The interference study was performed for the 22 potentially interfering substances that may be found in the upper respiratory tract. 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 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

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

e. 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

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

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
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

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
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 against *Mycobacterium tuberculosis* cannot be ruled out.

14. CLINICAL EVALUATION

14.1. CLINICAL STUDY – NASOPHARYNGEAL SWAB SPECIMENS

A prospective clinical study was conducted from January 2021 to February 2021 at point of care (POC) sites in the United States to evaluate the performance of the GenBody COVID-19 Ag test for direct nasopharyngeal swab specimens compared to an Emergency Use Authorized (EUA) RT-PCR test. A total of seven (7) operators from three (3) POC sites were involved in the study. Patients were prospectively and sequentially enrolled at each site. Samples were collected from patients of all ages who visited the doctor with signs and symptoms of suspected COVID-19. The performance of GenBody COVID-19 Ag test was established with 107 nasopharyngeal swab specimens collected from patients within 6 days of onset of COVID-19.

Two nasopharyngeal swabs were collected from each patient. One nasopharyngeal swab was tested directly with the GenBody COVID-19 Ag test according to the product instructions. The other swab was tested with the comparator RT-PCR. Swabs were randomly assigned to test with the GenBody COVID-19 Ag test or the RT-PCR.

A. Patient Demographic– Nasopharyngeal Swab Specimens Study

The patient demographic information (age, gender, and elapsed time from date of onset) is below.

Age Group	Male		Female		Total	
	No. of samples	%	No. of samples	%	No. of samples	%
≤5 years of age	0	0.00%	0	0.00%	0	0.00%
6-21 years of age	10	9.35%	12	11.21%	22	20.56%
22-59 years of age	33	30.84%	39	36.45%	72	67.29%
≥60 years of age	5	4.67%	8	7.48%	13	12.15%
Total	48	44.86%	59	55.14%	107	100.00%

Table a-1. The specimen positivity breakdown based on age and gender of the patient

Age Group	GenBody COVID-19 Ag		
	Total #	Positive	Prevalence
≤5 years of age	0	0	0.00%
6-21 years of age	22	9	40.91%
22-59 years of age	72	22	30.56%
≥60 years of age	13	10	76.92%
Total	107	41	38.32%

Table a-2. Positive results broken down by days since symptom onset

Days Since Symptom Onset	Cumulative RT-PCR Positive (+)	Cumulative GenBody COVID-19 Ag Positive (+)	PPA	95% Confidence Interval	
0	3	2	66.67%	9.43%	99.16%
1	11	9	81.82%	48.22%	97.72%
2	19	16	84.21%	60.42%	96.62%
3	24	21	87.50%	67.64%	97.34%
4	31	28	90.32%	74.25%	97.96%
5	42	38	90.48%	77.38%	97.34%
6	45	41	91.11%	78.78%	97.52%
Total	45	41	91.11%	78.78%	97.52%

B. Clinical Performance – Nasopharyngeal Swab Specimens Study

The performance of the GenBody COVID-19 Ag test compared to an EUA RT-PCR at all 3 combined POC sites is presented in the table below. A total of 107 patients were enrolled from all 3 sites with symptoms within 6 days of onset.

Table b-1. Summary of the performance of GenBody COVID-19 Ag compared with RT-PCR for all sites

All Sites		RT- PCR		
		Positive	Negative	Total
GenBody COVID-19 Ag	Positive	41	0	41
	Negative	4	62	66
	Total	45	62	107

	Estimate	95% CI	
		LCI	UCI
Sensitivity (% PPA)	91.1%	78.8%	97.5%
Specificity (% NPA)	100%	94.2%	100%
Prevalence	42.1%	32.6%	52.0%

14.2. CLINICAL STUDY – ANTERIOR NASAL SWAB SPECIMENS

A prospective clinical study was conducted from April 2021 to July 2021 at point of care (POC) sites in the United States to evaluate the performance of the GenBody COVID-19 Ag test for direct anterior nasal swab specimens compared to an Emergency Use Authorized (EUA) RT-PCR test. A total of eight (8) operators from five (5) POC sites were involved in the study. Patients were prospectively and sequentially enrolled at each site. Samples were collected from patients of all ages who visited the doctor with signs and symptoms of suspected COVID-19. The performance of GenBody COVID-19 Ag test was established with 169 anterior nasal swab specimens collected from patients within 6 days of onset of COVID-19.

An anterior nasal swab specimen was collected from each patient and tested directly with the GenBody COVID-19 Ag test. The test result was compared with the result of comparator RT-PCR that was performed with a nasopharyngeal swab specimen from the same patient.

A. Patient Demographics – Anterior Nasal Swab Specimens Study

The patient demographic information (age, gender, and elapsed time from date of onset) is below.

Age Group	Male		Female		Total	
	No. of samples	%	No. of samples	%	No. of samples	%
≤5 years of age	0	0.00%	1	0.59%	1	0.59%
6-21 years of age	18	10.65%	15	8.88%	33	19.53%
22-59 years of age	55	32.54%	66	39.05%	121	71.60%
≥60 years of age	7	4.14%	7	4.14%	14	8.28%
Total	80	47.34%	89	52.66%	169	100.00%

Table a-1. The specimen positivity breakdown based on age and gender of the patient

Age Group	GenBody COVID-19 Ag		
	Total #	Positive	Prevalence
≤5 years of age	1	0	0.00%
6-21 years of age	33	14	42.42%
22-59 years of age	121	45	37.19%
≥60 years of age	14	2	14.29%
Total	169	61	36.09%

Table a-2. Positive results broken down by days since symptom onset

Days Since Symptom Onset	Cumulative RT-PCR Positive (+)	Cumulative GenBody COVID-19 Ag Positive (+)	PPA	95% Confidence Interval	
0	4	4	100.00%	39.76%	100.00%
1	15	13	86.67%	59.54%	98.34%
2	30	28	93.33%	77.93%	99.18%
3	41	38	92.68%	80.08%	98.46%
4	54	49	90.74%	79.70%	96.92%
5	61	57*	91.80%**	81.90%**	97.28%**
6	65	61	92.31%**	82.95%**	97.46%**
Total	65	61	92.31%**	82.95%**	97.46%**

*1 false positive on onset date 5
**Calculated with 5 false negatives and 1 false positive

B. Clinical Performance – Anterior Nasal Swab Specimens Study

The performance of the GenBody COVID-19 Ag test compared to an EUA RT-PCR at all 5 combined POC sites is presented in the table below. A total of 169 patients were enrolled from all 5 POC sites with symptoms within 6 days of onset.

Table b-1. Summary of the performance of GenBody COVID-19 Ag compared with RT-PCR for all sites

All Sites		RT- PCR		
		Positive	Negative	Total
GenBody COVID-19 Ag	Positive	60	1	61
	Negative	5	103	108
	Total	65	104	169

	Estimate	95% CI	
		LCI	UCI
Sensitivity (% PPA)	92.31%	82.95%	97.46%
Specificity (% NPA)	99.04%	94.76%	99.98%
Prevalence	38.46%	31.09%	46.24%

14.3. 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 RTPCR, 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 C' below.

Table C. 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.

15. PERFORMANCE WITH ANALYTE CONCENTRATION NEAR THE LoD CONCENTRATION

To demonstrate that non-laboratory personnel can perform the GenBody COVID-19 Ag test accurately with weak positive samples in the intended use environment, a study was performed at 3 point of care (POC) sites by testing positive samples at 2x LoD and negative samples. A total of 6 operators who were medical assistants or nurses participated in the study (2 operators at each site).
Each operator performed tests blindly using the coded samples. All operators performed the GenBody COVID-19 Ag test accurately (100 % agreement with expected results) in the intended use environment.

16. 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).

17. ORDERING AND CONTACT INFORMATION

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

18. INTERNATIONAL SYMBOL USAGE

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

	Use-by date		Batch Code		*In vitro* diagnostic device
	Catalog number		Consult instructions for use		Manufacturer
	Contains sufficient for <n> test		Temperature limit		Do not reuse
	Caution		Test Device		Extraction Solution
	Dropper Tip		Positive Control Swab		Negative Control Swab

COVAG025-U-1 **[GenBody COVID-19 Ag packaged with NP swab]**
COVAG025-NU-1 **[GenBody COVID-19 Ag packaged with AN swab]**

Manufacturer
GenBody, Inc.
3-18, Eopseong 2-gil, Seobuk-gu
Cheonan-si, Chungcheongnam-do, 31077, Republic of Korea
Tel: +82-41-523-8993
Fax: +82-41-523-8991
Email: contact@genbody.co.kr
Website: http://genbody.co.kr

US Distributor / US Agent
Kwell Laboratories, LLC
3420 De Forest Circle
Jurupa Valley, CA 91752
USA
Tel: (949) 561-0664
Email: inquire@kwelllabs.com
Website: https://kwelllabs.com/

GenBody COVID-19 Ag Quick Reference Instructions

For Use Under an Emergency Use Authorization (EUA) Only

Date of Last Revision
2023.02.21 (Rev.5)

Intended Use

The GenBody COVID-19 Ag is an immunochromatographic rapid diagnostic test (RDT) intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in direct nasopharyngeal (NP) or anterior nasal (AN) swab specimens from individuals who are suspected of COVID-19 by their healthcare provider within the first six days of symptom onset when tested at least twice over three days with at least 48 hours between tests, or from 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. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform moderate, high, or waived complexity tests. This product is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance or Certificate of Accreditation.

Results are for the identification of SARS-CoV-2 nucleocapsid antigen. Antigen is generally detectable in nasopharyngeal (NP) or anterior nasal (AN) swab specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities.

All negative results are treated as presumptive and may be confirmed with a molecular assay, if necessary, for patient management. 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 measures such as isolating from others and wearing masks. Negative results should be considered in the context of a patient's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19.

The GenBody COVID-19 Ag is intended for use by medical professionals or operators trained in performing tests in point of care settings. The GenBody COVID-19 Ag is only for *in vitro* diagnostic use under the Food and Drug Administration's Emergency Use Authorization. This product has not been FDA cleared or approved.

Warnings, Precautions and Safety Information

- See Package Insert, including Quality Control section, for complete use instructions, warnings, precautions, and limitations.
- Read all instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate test results.
- **Serial testing should be performed in individuals with negative results at least twice over three days (with 48 hours between tests) for symptomatic individuals and three times over five days (with at least 48 hours between tests) for asymptomatic individuals. You may need to purchase additional tests to perform this serial (repeat) testing.**
- **If you have had symptoms longer than 6 days, you should consider testing at least three times over five days with at least 48 hours between tests.**

Conditions of Authorization

In the USA, this product has not been FDA cleared or approved, but has been authorized by FDA under an Emergency Use Authorization for use by authorized laboratories certified under the CLIA, 42 U.S.C. §263a, that meet requirements to perform moderate, high, or waived complexity tests. This product is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation. 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.

Contact Information

Technical Support (US)
Tel: (888) 552-5204
Email: ts@genbodyamerica.com

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

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

External Quality Control

Test control swabs included in the GenBody COVID-19 Ag kit in the same manner as patient specimens. The positive control should show a reddish-purple line at the C (Control) and T (Test) positions. The negative control should show a reddish-purple line at the C position only. If external controls do not perform as expected, do not use the test and contact Technical Support.

Swab Specimen Collection

Swab specimens collected from patients should be tested immediately after collection for best performance. The collected swab specimen can be tested for up to 60 minutes following specimen collection. The extracted specimen can be tested for up to 5 hours if stored between 2-30°C.

REF

COVAG025-U-1 **[GenBody COVID-19 Ag packaged with NP swab]**
COVAG025-NU-1 **[GenBody COVID-19 Ag packaged with AN swab]**

GenBody Inc.
CHANGE AND INNOVATION

IVD Rx ONLY

GenBody COVID-19 Ag Quick Reference Instructions

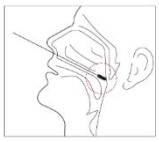
For Use Under an Emergency Use Authorization (EUA) Only

Date of Last Revision
2023.02.21 (Rev.5)

Part 1 – Sample Collection Procedure

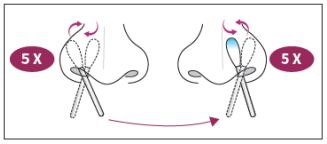
Refer to the CDC Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons for Coronavirus Disease 2019 (COVID-19).

Nasopharyngeal Samples



1) Remove a nasopharyngeal swab from the pouch.
2) With the patient's head tilted backwards at 70 degrees, carefully insert the swab into the nostril that presents the most secretion under visual inspection.
3) Gently and slowly insert the swab through the nostril parallel to the palate (not upwards) until resistance is encountered or the distance is equivalent to that from the ear to the nostril of the patient, indicating contact with the nasopharynx.
4) Leave the swab in place for several seconds to absorb secretions.
5) Rotate the swab 3-5 times against the posterior nasopharynx.
6) Using gentle rotation, remove the swab from the nostril; insert into the Extraction Tube.
7) All specimens should be tested as soon as they are prepared.

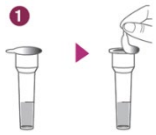
Anterior Nasal Samples



1) Remove an anterior nasal swab from the pouch.
2) Insert the Swab ½ to ¾ of an inch into the RIGHT nostril.
3) In a circular motion, rub the swab around the entire wall of the nostril with some pressure. This should be performed for at least 5 circles and 15 seconds.
4) Withdraw the swab and repeat the same process on the LEFT nostril.
5) Withdraw the swab from the second nostril. Immediately after BOTH nostrils have been swabbed, place the swab into the Extraction Tube.
6) All specimens should be tested as soon as they are prepared.

Part 2 – Test Procedure

Open the Test Device just prior to use, lay it flat, and perform assay as below.



[Step 1]
- **Peel off the foil cover** from the pre-filled tube.
- **Be careful to avoid spillage of the extraction solution**

[Step 2]
- **Insert** the collected specimen swab into the Extraction Solution.
- **Mix** by squeezing the tube and simultaneously twirling the swab 8-10 times. Remove the swab from the Extraction Tube while squeezing the swab against the side of the tube to extract the solution.
- Place the **Dropper Tip** on the Extraction Tube.

Inadequate sample extraction can result in incorrect results.

[Step 3]
- Place Test Device on a **level surface.**
- **Add 4 drops** of the solution to the center of the sample well of the Test Device.

[Step 4]
- **Read** the test result at **15-20 minutes.**
- **Do not read** the results after **20 minutes**.

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

Part 3 - Result Interpretation

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

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

Results should be considered in the context of an individual's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19.

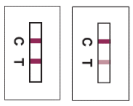
Negative Results

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.



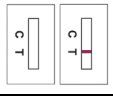
Positive Results

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 Results

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