GenBody COVID-19 Ag Quick Reference Instructions

Date of Last Revision
2021.11.17 (Rev.2)

For Use Under an Emergency Use Authorization (EUA) Only

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, or from individuals without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over two or three days with at least 24 hours and no more than 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.

Negative results should be 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 decisions. 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.

For serial testing programs, additional confirmatory testing with a molecular test for negative results 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. Additional confirmatory testing with a molecular test for positive results may also be necessary, if there is a low likelihood of SARS-CoV-2 infection, such as in individuals without known exposures to COVID-19 or residing in communities with low prevalence of infection.

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 use under the Food and Drug Administration's Emergency Use Authorization.

IMPORTANT

See Package Insert, including Quality Control section, for complete use instructions, warnings, precautions, and limitations.

Conditions of Authorization

In the USA, this product has not been FDA cleared or approved, but has been authorized by FDA under an EUA 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. In the USA, 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 the virus that causes 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

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

GenBody Inc.
CHANGE AND INNOVATION

IVD Rx ONLY

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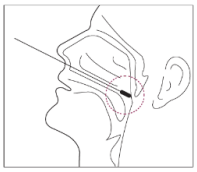
Part 1 – Sample Collection Procedure

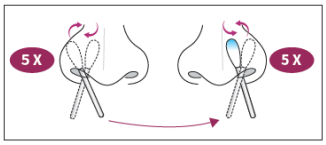
Refer to the CDC Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons for Coronavirus Disease 2019 (COVID-19).

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

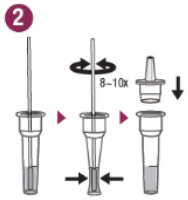


1) Remove an anterior nasal swab from the pouch.
2) Insert the Swab ½ to ¾ of an inch into the RIGHT nostril.
3) In a circular motion, rub the swab around the entire wall of the nostril with some pressure. This should be performed for at least 5 circles and 15 seconds.
4) Withdraw the swab and repeat 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

- **Add** the Extraction solution to the **Fill Line** indicated on the Extraction Tube.



- **Insert** the collected specimen swab into the Extraction Solution.
- **Mix** by squeezing the tube and simultaneously rotating the swab 8~10 times.
- Place the **Dropper Tip**.

Inadequate swab rotation can result in incorrect results.

- Place Test Device on a **level surface.**
- **Add 4 drops** of the solution to the sample well.

- **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

Laboratories within the United States and its territories are required to report all results to the appropriate public health laboratories.

Negative Results

Only one reddish purple line on the control line (C) position appears with no line on the test line position (T).

Note: If the first test result is negative for individuals without symptoms, individuals should be retested with a second test after 24 hours but no more than 48 hours. Negative results should be treated as presumptive and confirmed with a molecular assay, if necessary, for patient management.

Note: For serial testing programs, additional confirmatory testing with a molecular test for negative results 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.

Positive Results

Two reddish-purple lines appear in the test window, one on the test line position (T) and the other on the control line position (C).

Any visible reddish purple colored line at the T position is positive.

Note: Additional confirmatory testing with a molecular test for positive results may also be necessary if there is a low likelihood of SARS-CoV-2 infection, such as in individuals without known exposures to SARS-CoV-2 or residing in communities with low prevalence of infection.

Invalid Results

If a line does not appear on the control line position (C) in 15 minutes, the test result is invalid. Re-test with a new GenBody COVID-19 Ag Test Device.