FACT SHEET FOR HEALTHCARE PROVIDERS

GenBody Inc.

GenBody COVID-19 Ag August 10, 2022

Coronavirus Disease 2019 (COVID-19)

This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of the GenBody COVID-19 Ag test.

The GenBody COVID-19 Ag test is authorized for use using direct nasopharyngeal or anterior nasal swab specimens collected from individuals who are suspected of COVID-19 by their healthcare provider within the first 6 days of the onset of symptoms, 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.

All patients whose specimens are tested with this assay will receive the Fact Sheet for Patients: GenBody Inc. - GenBody COVID-19 Ag Test.

What are the symptoms of COVID-19?

Many patients with confirmed COVID-19 have developed fever and/or symptoms of acute respiratory illness (e.g., cough, dyspnea). The current information available to characterize the spectrum of clinical illness associated with COVID-19 suggests that symptoms include cough, shortness of breath or dyspnea, fever, chills, myalgias, headache, sore throat or new loss of taste or smell, nausea or vomiting or diarrhea. COVID-19 can present with a mild to severe illness, although some people with COVID-19 may have no symptoms at all. Signs and symptoms may appear any time from 2 to 14 days after exposure to the virus, and the median time to symptom onset is approximately 5 days. For further information on the symptoms of COVID-19 please see the link provided in the "*Where can I go for updates and more information*?" section.

Public health officials have identified cases of COVID-19 throughout the world, including the United States. Please check the CDC COVID-19 webpage (see link provided in the "*Where can I go for updates and more information*?" section at the end of this document) or your local jurisdiction's website for the most up to date information.

This test is to be performed only using direct nasopharyngeal (NP) or anterior nasal (AN) swab specimens collected from individuals who are suspected of COVID-19 by their healthcare provider within the first 6 days of the onset of symptoms, 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.

What do I need to know about COVID-19 testing?

Current information on COVID-19 for healthcare providers is available at the CDC's webpage, *Information for Healthcare Professionals* (see links provided in the "*Where can I go for updates and more information?*" section).

- The GenBody COVID-19 Ag Test can be used to test direct nasopharyngeal (NP) or anterior nasal (AN) swab samples directly.
- The GenBody COVID-19 Ag Test should be ordered for the detection of COVID-19 in individuals who are suspected of COVID-19 by their healthcare provider and who are within the first 6 days of onset of symptoms, or in 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.
- The GenBody COVID-19 Ag Test is authorized for use in laboratories in the United States, certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high, moderate or waived complexity tests. This test is not for home use.
- The GenBody COVID-19 Ag Test 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.
- Please refer to the GenBody COVID-19 Ag Package Inserts for additional information

Specimens should be collected with appropriate infection control precautions. Current guidance for COVID-19 control precautions is available at the CDC's website (see links provided in the "*Where can I go for updates and more information?*" section).

Use appropriate personal protective equipment when collecting and handling specimens from individuals suspected of having COVID-19 as outlined in the CDC *Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 (*COVID-*19)*. For additional information, refer to CDC *Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons Under Investigation (PUIs) for Coronavirus Disease 2019* (COVID-19) (see links provided in the "Where can I go for updates and more information" section).

What does it mean if the specimen tests positive for the virus that causes COVID-19?

A positive test result for COVID-19 indicates that nucleocapsid antigens from SARS-CoV-2 were detected, and the patient is infected with the virus and presumed to be contagious. Laboratory test results should always be considered in the context of clinical observations and epidemiological data (such as local prevalence rates and current outbreak/epicenter locations) in making a final diagnosis and patient management decisions. Patient management should follow current CDC guidelines.

The GenBody COVID-19 Ag Test has been designed to minimize the likelihood of false positive test results. However, in the event of a false positive result, risks to patients could include the following: a recommendation for isolation of the patient, monitoring of household or other close contacts for symptoms, patient isolation that might limit contact with family or friends and may increase contact with other potential COVID-19 patients, limits in the ability to work, the delayed diagnosis and treatment for the true infection causing the symptoms, unnecessary prescription of a treatment or therapy, or other unintended adverse effects.

All laboratories using this test must follow the standard testing and reporting guidelines according to their appropriate public health authorities.

What does it mean if the specimen tests negative for the virus that causes COVID-19?

A negative test result for this test means that nucleocapsid antigens from SARS-CoV-2 were not present in the specimen above the limit of detection. However, a negative result does not rule out COVID-19 and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Antigen tests are known to be less sensitive than molecular tests that detect viral nucleic acids.

The amount of antigen in a sample may decrease as the duration of illness increases. Specimens collected after day 6 of illness may be more likely to be negative compared to a RT-PCR assay. Therefore, negative results from patients with symptom onset beyond 6 days should be treated as presumptive and confirmed with a molecular assay, if necessary, for patient management. When diagnostic testing is negative, the possibility of a false negative result should be considered in the context of a patient's recent exposures and the presence of clinical signs and symptoms consistent with COVID-19.

When diagnostic testing is negative, the possibility of a false negative result should especially be considered if the patient's recent exposures or clinical presentation indicate that COVID-19 is likely, and diagnostic tests for other causes of illness (e.g., other respiratory illness) are negative. If COVID-19 is still suspected based on exposure history together with other clinical findings, re-testing or testing with molecular methods should be considered by healthcare providers in consultation with public health authorities.

Risks from a false negative result include: delay or lack of supportive treatment, lack of monitoring of infected individuals and their household or other close contacts for symptoms resulting in increased risk of spread of COVID-19 within the community, or other unintended adverse events.

A negative antigen test should not be the sole basis used to determine if a patient can end isolation precautions. For additional recommendations regarding infection control, refer to the CDC's *Discontinuation of Isolation for Persons with COVID-19 Not in Healthcare Settings* (Interim Guidance) (see links provided in the "Where can I go for updates and more

information" section).

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 (for nasopharyngeal samples) and between April 2021 to July 2021 (for anterior nasal samples). The clinical performance has not been established in 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.

Clinical performance using direct nasopharyngeal or anterior nasal swab specimens collected from patients without symptoms or other epidemiological reasons to suspect SARS-CoV-2 infection, or for serial screening when tested twice over three days with at least 48 hours between tests has not been determined. A study to support use will be completed.

What do I need to know about Serial Testing in Asymptomatic Individuals?

In asymptomatic patients, serial testing may assist in identifying infected individuals and facilitate timely infection control practices. A negative test result does not rule out infection but repeat testing over two or three days may decrease the risk of false negative results. An initial negative test result should be the first of a minimum of two tests. An asymptomatic individual undergoing serial testing with two or more negative results may require ongoing serial testing or confirmatory testing, depending on patient history and potential exposures. An asymptomatic individual undergoing serial testing with one or more positive results indicates that SARS-CoV-2 antigen is present but does not rule out coinfection with other pathogens.

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 a close contact with COVID-19, a 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 SARS-CoV-2 or residing in communities with low prevalence of infection. For additional recommendations regarding confirmation of antigen test results, please refer to the CDC's Interim Guidance for Antigen Testing for SARS-CoV-2 (see links provided in "*Where can I go for updates and more information?*" section).

What is an EUA?

The United States FDA has made this test available under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA is supported by the Secretary of Health and Human Service's (HHS's) declaration that circumstances exist to justify the emergency use of diagnostics (IVDs) for the detection and/or diagnosis of the virus that causes COVID-19.

An IVD made available under an EUA has not undergone the same type of review as an FDA-approved or cleared IVD. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, available alternatives, and based on the totality of scientific evidence available, it is reasonable to believe that this IVD may be effective in diagnosing COVID-19.

The EUA for this test is in effect for the duration of the COVID-19 declaration justifying emergency use of IVDs, unless terminated or revoked (after which the test may no longer be used).

What are the approved available alternatives?

There are no approved available alternative antigen tests. Any tests that have received full marketing status (e.g., cleared, approved), as opposed to an EUA, by FDA can be found by searching the medical device databases here:

https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases

A cleared or approved test should be used instead of a test made available under an EUA, when appropriate and available. FDA has issued EUAs for other tests that can be found at:

https://www.fda.gov/emergency-preparedness-

and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization

Where can I go for updates and more information?

CDC webpages:

General: https://www.cdc.gov/coronavirus/2019-ncov/index.html
Symptoms: https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html
Healthcare Professionals: https://www.cdc.gov/coronavirus/2019-nCoV/hcp/index.html
Information for Laboratories: https://www.cdc.gov/coronavirus/2019-nCoV/lab/index.html
Laboratory Biosafety: https://www.cdc.gov/coronavirus/2019-nCoV/lab/lab-biosafety-guidelines.html
Isolation Precautions in Healthcare Settings: https://www.cdc.gov/infectioncontrol/guidelines/isolation/index.html
Specimen Collection: https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html
Infection Control: https://www.cdc.gov/coronavirus/2019-ncov/php/infection-control.html

FDA webpages:

General: www.fda.gov/novelcoronavirus
EUAs: (includes links to patient fact sheet and manufacturer's instructions) https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas

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