



August 10, 2022

Han-bum Park, RA
GenBody Inc.
3-18, Eopseong 2-gil, Seobuk-gu, Cheonan-si,
Chungcheongnam-do, 31077 Republic of Korea

Device: GenBody COVID-19 Ag
EUA Number: EUA210249
Company: GenBody Inc.
Indication: 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. Emergency use of this test is limited to authorized laboratories.

Authorized Laboratories: 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.

Dear Han-bum Park:

On July 13, 2021, based on your¹ request the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for emergency use of the GenBody COVID-19 Ag test, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3) for the indications stated in the letter.² Based on your request, the July 13, 2021,

¹ For ease of reference, this letter will use the term “you” and related terms to refer to GenBody Inc.

² The July 13, 2021, letter authorized your product for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in direct nasopharyngeal swab (NP) specimens from individuals who are suspected of COVID-19 by their healthcare provider within the first six days of symptom onset. Emergency use of this test was 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 test was authorized for use at

letter was revised and reissued by FDA on September 24, 2021,³ and November 17, 2021.⁴ FDA also granted an update on June 13, 2022.⁵

On June 13, 2022, you requested to amend your EUA. Based on that request, and having concluded that revising the November 17, 2021, EUA is appropriate to protect the public health or safety under section 564(g)(2)(C) of the Act (21 U.S.C. § 360bbb-3(g)(2)(C)), FDA is reissuing the November 17, 2021, letter in its entirety with the revisions incorporated.⁶ Accordingly, your product⁷ is hereby authorized pursuant to section 564 of the Act when used pursuant to the Scope of Authorization (Section II) and Conditions of Authorization (Section IV) of this reissued letter.

On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Act, the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes COVID-19. Pursuant to Section 564 of the Act, and on the basis of such determination, the Secretary of HHS then declared 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 subject to the terms of any authorization issued under Section 564(a) of the Act.⁸

FDA considered the totality of scientific information available in authorizing the emergency use of your product for the indication above. A summary of the performance information FDA relied upon is included in the “GenBody COVID-19 Ag Instructions for Use (IFU)” (identified below).

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.

³ On September 24, 2021, the revisions to the July 13, 2021, letter and authorized labeling included: (1) updates to the intended use to add anterior nasal (AN) swab specimens as an authorized specimen type; (2) updates to the performance data to include results of clinical testing AN swab specimens; (3) removal of Condition of Authorization Q. in the July 13, 2021, that was fulfilled as part of the revision request; and (4) updates to the Fact Sheet for Healthcare Providers to reflect the updated intended use and updating the date on the Fact Sheet for Patients to match the date of re-issuance of the letter.

⁴ The revisions to the September 24, 2021, letter and authorized labeling include: (1) updates to the intended use to include use of your product with testing of direct nasopharyngeal (NP) or anterior nasal (AN) swab specimens “*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,*” (2) updates to reflect the updated intended use, including addition of Condition of Authorization S. and T., and (3) updates for consistency with language used in more recent authorizations.

⁵ On June 13, 2022, FDA granted your request to extend the shelf-life expiration date to 21 months, when stored at 2°C – 30°C, based on the results of your ongoing stability studies.

⁶ The revisions to the November 17, 2021, letter and authorized labeling include: (1) updates to the assay labeling reflecting updated kit configuration and test procedure to use individual pre-filled extraction solution tubes, and (2) updates to the Healthcare Provider (HCP) and Recipient Fact Sheets to reflect language used in more recent authorizations.

⁷ For ease of reference, this EUA will use the term “your product” to refer to the GenBody COVID-19 Ag used for the indication identified above.

⁸ U.S. Department of Health and Human Services, *Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act*, 21 U.S.C. § 360bbb-3. 85 FR 7316 (February 7, 2020).

Having concluded that the criteria for issuance of this authorization under Section 564(c) of the Act are met, I am authorizing the emergency use of your product, described in the Scope of Authorization of this letter (Section II), subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of your product meets the criteria for issuance of an authorization under Section 564(c) of the Act, because I have concluded that:

1. The SARS-CoV-2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus;
2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that your product may be effective in diagnosing COVID-19, and that the known and potential benefits of your product when used for diagnosing COVID-19, outweigh the known and potential risks of your product; and
3. There is no adequate, approved, and available alternative to the emergency use of your product.⁹

II. Scope of Authorization

I have concluded, pursuant to Section 564(d)(1) of the Act, that the scope of this authorization is limited to the indication above.

Authorized Product Details

Your product is an immunochromatographic rapid diagnostic test 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.

The SARS-CoV-2 nucleocapsid protein antigen is generally detectable in NP or AN swab specimens during the acute phase of infection. Positive results indicate the presence of the viral antigen, 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.

Negative results should be treated as presumptive and confirmation 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

⁹ No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

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 SARS-CoV-2 or residing in communities with low prevalence of infection

Testing of NP and AN swab specimens using your product, as outlined in the “GenBody COVID-19 Ag Instructions for Use (IFU)” is limited to laboratories certified under CLIA 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.

To use your product, the clinical specimen is tested and the results interpreted according to the test procedures described in the authorized labeling (described below). The GenBody COVID-19 Ag test includes use of materials or other authorized materials (as may be requested under Condition N. below) required to perform testing with your product as described in the “GenBody COVID-19 Ag Instructions for Use (IFU)”, and “GenBody COVID-19 Ag Quick Reference Instructions.”

Your product requires various types of quality control, including the procedural internal control that is built in the “control line” of the test device and the external positive and negative controls, or other authorized control materials (as may be requested under Condition N. below). Controls are run as outlined in the “GenBody COVID-19 Ag Instructions for Use (IFU)”, and “GenBody COVID-19 Ag Quick Reference Instructions.”

Your product also requires the use of additional authorized materials and authorized ancillary reagents that are not included with your product and are described in the Instructions for Use.

The labeling entitled “GenBody COVID-19 Ag Instructions for Use (IFU),” “GenBody COVID-19 Ag Quick Reference Instructions” (available at <https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas>), and the following fact sheets pertaining to the emergency use, is required to be made available as set forth in the Conditions of Authorization (Section IV), and are collectively referred to as “authorized labeling”:

- Fact Sheet for Healthcare Providers: GenBody Inc. - GenBody COVID-19 Ag
- Fact Sheet for Patients: GenBody Inc. - GenBody COVID-19 Ag

The above described product, when accompanied by the authorized labeling provided as set forth in the Conditions of Authorization (Section IV), is authorized to be distributed to and used by

authorized laboratories under this EUA, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

I have concluded, pursuant to Section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of your product, when used consistent with the Scope of Authorization of this letter (Section II), outweigh the known and potential risks of your product.

I have concluded, pursuant to Section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that your product may be effective in diagnosing COVID-19, when used consistent with the Scope of Authorization of this letter (Section II), pursuant to Section 564(c)(2)(A) of the Act.

FDA has reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, and concludes that your product (as described in the Scope of Authorization of this letter (Section II)) meets the criteria set forth in Section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of your product under this EUA must be consistent with, and may not exceed, the terms of this letter, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section IV). Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination under Section 564(b)(1)(C) of the Act described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1) of the Act, your product is authorized for the indication above.

III. Waiver of Certain Requirements

I am waiving the following requirements for your product during the duration of this EUA:

- Current good manufacturing practice requirements, including the quality system requirements under 21 CFR Part 820 with respect to the design, manufacture, packaging, labeling, storage, and distribution of your product, but excluding Subpart H (Acceptance Activities, 21 CFR 820.80 and 21 CFR 820.86), Subpart I (Nonconforming Product, 21 CFR 820.90), and Subpart O (Statistical Techniques, 21 CFR 820.250).

IV. Conditions of Authorization

Pursuant to Section 564(e) of the Act, I am establishing the following conditions on this authorization:

GenBody Inc. (You) and Authorized Distributor(s)¹⁰

¹⁰ “Authorized Distributor(s)” are identified by you, GenBody Inc., in your EUA submission as an entity allowed to distribute your product.

- A. Your product must comply with the following labeling requirements under FDA regulations: the intended use statement (21 CFR 809.10(a)(2), (b)(2)); adequate directions for use (21 CFR 809.10(b)(5), (7), and (8)); appropriate limitations on the use of the device including information required under 21 CFR 809.10(a)(4); and any available information regarding performance of the device, including requirements under 21 CFR 809.10(b)(12).
- B. You and authorized distributor(s) must make your product available with the authorized labeling to authorized laboratories.
- C. You and authorized distributor(s) must make available on your website(s) the authorized labeling.
- D. You and authorized distributor(s) will include a physical copy of the “GenBody COVID-19 Ag Instructions for Use (IFU),” and the “GenBody COVID-19 Ag Quick Reference Instructions” with each shipped kit of your product to authorized laboratories.
- E. You and authorized distributor(s) must inform authorized laboratories and relevant public health authorities of this EUA, including the terms and conditions herein, and any updates made to your product and authorized labeling.
- F. Through a process of inventory control, you and authorized distributor(s) must maintain records of the authorized laboratories to which they distribute your product and number distributed.
- G. You and authorized distributor(s) must collect information on the performance of your product. You will report to the Division of Microbiology (DMD)/Office of Health Technology 7 (OHT7)-Office of In Vitro Diagnostics and Radiological Health (OIR)/Office of Product Evaluation and Quality (OPEQ)/Center for Devices and Radiological Health (CDRH) (via email: CDRH-EUA-Reporting@fda.hhs.gov) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of the product of which you become aware.
- H. You and authorized distributor(s) are authorized to make available additional information relating to the emergency use of your product that is consistent with, and does not exceed, the terms of this letter of authorization.

GenBody Inc. (You)

- I. You must notify FDA of any authorized distributor(s) of your product, including the name, address, and phone number of any authorized distributor(s).
- J. You must provide authorized distributor(s) with a copy of this EUA and communicate to authorized distributor(s) any subsequent revisions that might be made to this EUA

and its authorized accompanying materials (e.g., Fact Sheets).

- K. You must comply with the following requirements pursuant to FDA regulations: 21 CFR 820 Subpart H (Acceptance Activities, 21 CFR 820.80 and 21 CFR 820.86), Subpart I (Nonconforming Product, 21 CFR 820.90), and Subpart O (Statistical Techniques, 21 CFR 820.250).
- L. You must have lot release procedures and the lot release procedures, including the study design and statistical power, must ensure that the tests released for distribution have the clinical and analytical performance claimed in the authorized labeling.
- M. If requested by FDA, you must submit lot release procedures to FDA, including sampling protocols, testing protocols, and acceptance criteria, that you use to release lots of your product for distribution in the U.S. If such lot release procedures are requested by FDA, you must provide it within 48 hours of the request.
- N. You may request changes to this EUA for your product, including to the Scope of Authorization (Section II in this letter) or to the authorized labeling, including requests to make available additional authorized labeling specific to an authorized distributor. Such additional labeling may use another name for the product but otherwise must be consistent with the authorized labeling and shall not exceed the terms of authorization of this letter. Any request for changes to this EUA should be submitted to DMD/OHT7-OIR/OPEQ/CDRH and require appropriate authorization from FDA prior to implementation.
- O. You must evaluate the analytical limit of detection and assess traceability¹¹ of your product with any FDA-recommended reference material(s). After submission to and review and concurrence with the data by FDA, you must update labeling to reflect the additional testing. Such labeling updates must be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.
- P. You must have a process in place to track adverse events, including any occurrence of false results and report to FDA pursuant to 21 CFR Part 803.
- Q. You must evaluate the impact of SARS-CoV-2 viral mutations on your product's performance. Such evaluations must occur on an ongoing basis and must include any additional data analysis that is requested by FDA in response to any performance concerns you or FDA identify during routine evaluation. Additionally, if requested by FDA, you must submit records of these evaluations for FDA review within 48 hours of the request. If your evaluation identifies viral mutations that affect the stated expected performance of your device, you must notify FDA immediately (via email: CDRH-EUAREporting@fda.hhs.gov).
- R. If requested by FDA, you must update your labeling within 7 calendar days to include

¹¹ Traceability refers to tracing analytical sensitivity/reactivity back to an FDA-recommended reference material.

any additional labeling risk mitigations identified by FDA, such as those related to the impact of viral mutations on test performance. Such updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

- S. You must evaluate the clinical performance of your product to support the serial screening claim in an FDA agreed upon post authorization clinical evaluation study within 6 months of the date of this letter (unless otherwise agreed to with DMD/OHT7-OIR/OPEQ/CDRH). After submission to and concurrence with the data by FDA, you must update the authorized labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.
- T. You must submit your product for any independent evaluation to confirm the performance characteristics of your test, if requested by FDA, and in the manner requested by FDA. After submission to and concurrence with the data by FDA, you will update your labeling to reflect the additional evaluation. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

Authorized Laboratories

- U. Authorized laboratories using your product must include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating this labeling may be used, which may include mass media.
- V. Authorized laboratories using your product must use your product as outlined in the authorized labeling. Deviations from the authorized procedures, including authorized instruments, authorized clinical specimen types, authorized control materials, authorized ancillary reagents and authorized materials required to use your product are not permitted.
- W. Authorized laboratories that receive your product must notify the relevant public health authorities of their intent to run your product prior to initiating testing.
- X. 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.
- Y. 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 you (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.
- Z. 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 authorized labeling.

GenBody Inc. (You), Authorized Distributor(s) and Authorized Laboratories

AA. You, authorized distributor(s), and authorized laboratories using your product must ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

Conditions Related to Printed Materials, Advertising and Promotion

BB. All descriptive printed matter, advertising and promotional materials relating to the use of your product shall be consistent with the authorized labeling, as well as the terms set forth in this EUA and meet the requirements set forth in section 502(a), (q)(1), and (r) of the Act, as applicable, and FDA implementing regulations.

CC. No descriptive printed matter, advertising or promotional materials relating to the use of your product may represent or suggest that this test is safe or effective for the detection of SARS-CoV-2.

DD. All descriptive printed matter, advertising and promotional materials relating to the use of your product shall clearly and conspicuously state that:

- This product has not been FDA cleared or approved, but has been authorized by FDA under an EUA for use by authorized laboratories;
- This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens; and,
- 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.

The emergency use of your product as described in this letter of authorization must comply with the conditions and all other terms of this authorization.

V. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Sincerely,

Namandjé N. Bumpus, Ph.D.
Chief Scientist
Food and Drug Administration

Enclosure

cc: David Yoo, CEO, Kwell Laboratories, LLC (U.S. Agent), clinical@kwelllabs.com