



December 13, 2022

In-Kyung Hong
Associate Manager, RA
Seegene Inc.
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Device: Allplex 2019-nCoV Assay

EUA Number: EUA200119

Company: Seegene, Inc.

Indication: This test is authorized for the qualitative detection of nucleic acid from SARS-CoV-2 in human nasopharyngeal swab, oropharyngeal swab, anterior nasal swab, mid-turbinate, nasopharyngeal wash/aspirate, nasal aspirate, bronchoalveolar lavage (BAL) and sputum specimens from individuals who are suspected of COVID-19 by their health care provider.

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, to perform high complexity tests.

Dear In-Kyung Hong:

On April 21, 2020, based on your¹ request, the Food and Drug Administration (FDA) issued a letter authorizing the emergency use of the Allplex 2019-nCoV Assay for the qualitative detection of nucleic acid from SARS-CoV-2 in human nasopharyngeal swab, oropharyngeal swab, anterior nasal swab, mid-turbinate and sputum specimens from individuals who are suspected of COVID-19 by their health care provider, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3). Testing was limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests. Based on your request, FDA granted updates to the authorized labeling on July 27, 2020.² In addition, FDA established additional

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

² On July 27, 2020, your request was granted to update the Instructions for Use (IFU) of your product to: (1) add additional extraction methods for use with the test, STARMag 96 x 4 Universal Cartridge Kit (extraction kit) (Seegene) using Microlab NIMBUS IVD instrument (Microlab), STARMag 96 X 4 Viral DNA/RNA 200 C Kit (extraction kit) (Seegene) using Microlab STARlet IVD instrument (Microlab), AdvanSure NA EX Kit (extraction kit) using AdvanSure E3 Instrument System (LG Chem), QIAamp DSP Viral Mini Kit using QIAcube instrument

Conditions of Authorization in response to the continued emergence of new variants of SARS-CoV-2 on September 23, 2021.³

On January 15, 2021 and on December 6, 2021, you requested to amend your Emergency Use Authorization (EUA). Based on that request, and having concluded that revising the April 21, 2020, 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 April 21, 2020, letter in its entirety with the revisions incorporated.⁴ Pursuant to section 564 of the Act and the Scope of Authorization (Section II) and Conditions of Authorization (Section IV) of this reissued letter, your product⁵ is now intended for the indications described above.

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.⁶

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 Instructions for Use (identified below).

Having concluded that the criteria for issuance of this authorization under Section 564(c) of the

(QIAgen), Ribospin vRD Viral RNA/DNA Extraction Kit (GeneAll) (manual), MagMAX Viral/Pathogen Nucleic Acid Isolation Kit, using KingFisher Flex instrument and the MagNA Pure DNA and Viral NA Small Volume Kit using Roche MagNA Pure 96, (2) add two real-time PCR instruments, the Applied Biosystem 7500 Real-Time PCR (AB7500) and the Applied Biosystem 7500 Fast Dx Real-Time PCR instrument (AB7500 Fast Dx)], for use with the test, (3) update the in silico inclusivity testing in the performance section, and (4) make some general minor edits and clarifications. FDA also included some minor updates to the intended use to reflect language used in more recent authorizations and the Healthcare Provider and Patient Fact Sheets were updated accordingly.

³ The Viral Mutation Revision Letter – September 23, 2021, can be accessed at:

<https://www.fda.gov/media/152406/download>.

⁴ The revisions to the April 21, 2020, letter and authorized labeling include: (1) addition of the “Allplex 2019-nCoV Assay Product Information Card” to the authorized labeling, (2) updates to the LoD data to establish the assay LoD using whole inactivated virus, (3) addition of new PCR consumables and PCR instrumentation for use with the test, Bio-Rad’s CFX Dx (CFX Manager Dx Software v3.1) and CFX Opus Dx Real-time Detection System (CFX Maestro Software V2.0), (4) addition of new LoD testing data supporting equivalent performance of the new PCR consumables and PCR instruments, (5) an update to the Assay Limitations section to fulfill Conditions of Authorization included in the September 23, 2021 Viral Mutation Revision Letter, (6) updates to the Warnings and Precautions section to reflect language used in more recent authorizations, (7) updates to the in silico inclusivity analysis, (8) addition of an Emergency Use Only sticker for Research Use Only instruments, (9) minor edits and clarifications to the IFU and update to the indication specimen types, and (10) updates to the Fact Sheet for Healthcare Providers and the Fact Sheet for Patients to reflect language used in more recent authorizations.

⁵ For ease of reference, this letter will use the term “your product” to refer to the Allplex 2019-nCoV Assay used for the indication identified above.

⁶ 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).

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.⁷

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 *in vitro* diagnostic (IVD) real-time reverse transcriptase polymerase chain reaction (RT-PCR) test intended for the qualitative detection of SARS-CoV-2 viral nucleic acids in human nasopharyngeal swab, oropharyngeal swab, anterior nasal swab, mid-turbinate nasopharyngeal wash/aspirate, nasal aspirate, bronchoalveolar lavage (BAL) and sputum specimens from individuals who are suspected of COVID-19 by their health care provider. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high complexity tests.

Results are for the identification of SARS-CoV-2 RNA. The SARS-CoV-2 RNA is generally detectable in respiratory specimens during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2 RNA; clinical correlation with patient history and other diagnostic information is necessary to determine patient 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 do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

⁷ No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

To use your product, SARS-CoV-2 nucleic acid is first extracted, isolated and purified from nasopharyngeal swab, oropharyngeal swab, anterior nasal swab, mid-turbinate nasopharyngeal wash/aspirate, nasal aspirate, bronchoalveolar lavage (BAL) and sputum specimens. The purified nucleic acid is then reverse transcribed into cDNA followed by PCR amplification and detection using an authorized real-time (RT) PCR instrument. The Allplex 2019-nCoV Assay includes the materials (or other authorized materials as may be requested under Condition K. below) described in the Instructions for Use.

Your product requires control materials (or other authorized control materials as may be requested under Condition K. below) that are described in the Instructions for Use.

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 “Allplex 2019-nCoV Assay Instructions for Use” and “Allplex 2019-nCoV Assay Product Information Card” (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, are 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: Seegene, Inc. - Allplex 2019-nCoV Assay
- Fact Sheet for Patients: Seegene, Inc. - Allplex 2019-nCoV Assay

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 consistently 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:

Seegene, Inc. (You) and Authorized Distributor(s)⁸

- A. Your product must comply with the following labeling requirements: the intended use statement (21 CFR 809.10(a)(2), (b)(2)); adequate directions for use (21 U.S.C. 352(f)), (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) must include a physical copy of the “Allplex 2019-nCoV Assay Product Information Card” with each shipped product to authorized laboratories, and must make the authorized “Allplex 2019-nCoV Assay Instructions for Use” electronically available with the opportunity to request a copy in paper form, and after such request, you must promptly provide the requested information without additional cost.
- 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.

⁸ “Authorized Distributor(s)” are identified by you, Seegene, Inc., in your EUA submission as an entity allowed to distribute your product.

- 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 of your product they distribute.
- G. You and authorized distributor(s) must collect information on the performance of your product. You must report to FDA any suspected occurrence of false positive and false negative results and significant deviations from the established performance characteristics of your 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.

Seegene, 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 amendments that might be made to this EUA and its authorized accompanying materials (e.g., Fact Sheets).
- K. You may request changes to this EUA for your product, including 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 not exceed the terms of authorization of this letter. Any request for changes to this EUA should be submitted to the Division of Microbiology (DMD)/Office of Health Technology 7 (OHT7): Office of In Vitro Diagnostics/Office of Product Evaluation and Quality (OPEQ)/Center for Devices and Radiological Health (CDRH) and require appropriate authorization from FDA prior to implementation.
- L. 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).
- M. 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.
- N. 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.

- O. You must evaluate the analytical limit of detection and assess traceability⁹ of your product with any FDA-recommended reference material(s). After submission to and concurrence with the data by FDA, you must update your labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7/OPEQ/CDRH.
- P. You must have a process in place to track adverse events, including any occurrence of false results with your product 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-EUA-Reporting@fda.hhs.gov).
- R. If requested by FDA, you must update your labeling within 7 calendar days to include any additional labeling risk mitigations identified by FDA regarding the impact of viral mutations on test performance. Such updates will be made in consultation with, and require concurrence of, DMD/OHT7/OPEQ/CDRH.

Authorized Laboratories

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

⁹ Traceability refers to tracing analytical sensitivity/reactivity back to an FDA-recommended reference material.

report to DMD/OHT7/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and you (support@segenetech.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.

- X. All laboratory personnel using your product must be appropriately trained in RT-PCR techniques and use appropriate laboratory and personal protective equipment when handling this kit, and use your product in accordance with the authorized labeling.

Seegene, Inc. (You), Authorized Distributors and Authorized Laboratories

- Y. 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 must be made available to FDA for inspection upon request.

Conditions Related to Advertising and Promotion

- Z. 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 section 502(a), (q)(1), and (r) of the Act, as applicable, and FDA implementing regulations.
- AA. 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.
- BB. 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 for emergency use by FDA under an EUA for use by authorized laboratories;
 - This product has been authorized only for the detection of nucleic acid 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