September 7, 2021

Greer Massey, Ph.D.
Assurance Scientific Laboratories
2868 Acton Road
Birmingham, AL 35243

Device:	Assurance SARS-CoV-2 Panel DTC
EUA Number:	EUA210025
Company:	Assurance Scientific Laboratories
Indication:	A direct to consumer product for testing of anterior nasal swab specimens collected at home using either: (1) the Simplicity COVID-19 Home Collection Kit by any individuals, 18 years and older, including individuals without symptoms or other reasons to suspect COVID-19 or (2) the Everlywell COVID-19 Test Home Collection Kit DTC when used consistent with its authorization. The Assurance SARS-CoV-2 Panel DTC is limited to authorized laboratories.
Authorized Laboratories:	Testing is limited to laboratories designated by Assurance Scientific Laboratories, that are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C.§263, and meet the requirements to perform high-complexity tests.

Dear Dr. Massey:

On February 13, 2021, based on your[1] request the Food and Drug Administration (FDA) issued a letter authorizing the emergency use of the Assurance SARS-CoV-2 Panel DTC as a direct to consumer product for testing of anterior nasal swab specimens self-collected at home using either: (1) the Simplicity COVID-19 Home Collection Kit or (2) the Everlywell COVID-19 Test Home Collection Kit DTC by any individuals, 18 years and older, including individuals without symptoms or other reasons to suspect COVID-19, 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 designated by Assurance Scientific Laboratories, that are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C.§263, and meet the

[1] For ease of reference, this letter will use the term "you" and related terms to refer to Assurance Scientific Laboratories.

requirements to perform high-complexity tests. Based on your requests FDA reissued the letter in its entirety on July 1, 2021.[2]

On September 7, 2021, based on your request and having concluded that revising the July 1, 2021, EUA is appropriate to protect 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 July 1, 2021, letter in its entirety with the revisions incorporated.[3] 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 product[4] 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.[5]

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 contained in the EUA Summary (identified below).

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:

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[2] On July 1, 2021, the revisions to the February 13, 2021, letter and authorized labeling included: (1) updating use of the Everlywell COVID-19 Test Home Collection Kit to specify "when used consistent with its authorization," (2) updates to the EUA Summary, Laboratory SOPs, Fact Sheet for Healthcare Providers and Fact Sheet to Patients to reflect the updated intended use and reflect language used in more recent authorizations, and (3) updating the Conditions of Authorization as a result of the change to the intended use and to reflect language used in more recent authorizations..

[3] The revisions to the July 1, 2021, letter and authorized labeling include: (1) update the EUA Summary to include the results of of testing low positive specimens as required as a Condition of Authorization (Condition O. in the July 1, 2021, letter) (2) updates to the Conditions of Authorization to add new Conditions related to circulating SARS-CoV-2 variants (Conditions O. and P. below), delete Condition O. from the July 1, 2021, that was fulfilled via data submitted to FDA and update Condition N. to focus on reporting from the Simplicity COVID-19 Home Collection Kit; and (4) the date on the Fact Sheet for Healthcare Providers and the Fact Sheet for Patients was updated to match the date of re-issuance of the letter.

[4] For ease of reference, this letter will use the term "your product" to refer to the Assurance SARS-CoV-2 Panel DTC used for the indication identified above.

[5] 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).

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.[6]

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

The Assurance SARS-CoV-2 Panel DTC is a direct to consumer product for testing of anterior nasal swab specimens collected at home using either: (1) the Simplicity COVID-19 Home Collection Kit by any individuals, 18 years and older, including individuals without symptoms or other reasons to suspect COVID-19; or (2) the Everlywell COVID-19 Test Home Collection Kit DTC when used consistent with its authorization.

Testing of collected anterior nasal swab specimens is limited to laboratories designated by Assurance Scientific Laboratories, that are certified under CLIA, 42 U.S.C.§263, and meet the requirements to perform high-complexity tests.

All test results from specimens collected with the Simplicity COVID-19 Home Collection Kit are delivered to the user via an online portal. Individuals with positive and invalid/indeterminate results additionally will be contacted by a healthcare provider.[7] The direct to consumer home collection system is intended to enable users to access information about their COVID-19 infection status that could aid with determining if isolation or quarantine is appropriate and to assist with healthcare decisions after discussion with a healthcare provider.

Results are for the identification of SARS-CoV-2 RNA. The SARS-CoV-2 RNA is generally detectable in anterior nasal swab specimens during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2 RNA; clinical correlation with medical 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

[6] No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.
[7] For this EUA, a healthcare provider includes any health professional with prescribing abilities, including, but is not limited to, physicians, nurses, pharmacists, technologists, laboratory directors, and epidemiologists.

to report all results to the appropriate public health authorities. Negative results do not preclude SARS-CoV-2 infection.

Use of your product is not a substitute for visits to a healthcare provider. The information provided by this product should not be used to start, stop, or change any course of treatment unless advised by your healthcare provider.

To use your product, SARS-CoV-2 nucleic acid is first extracted, isolated and purified from anterior nasal swab specimens collected at home using either the Simplicity COVID-19 Home Collection Kit or the Everlywell COVID-19 Test Home Collection Kit DTC. 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 Assurance SARS-CoV-2 Panel DTC uses all commercially sourced materials or other authorized materials and authorized ancillary reagents commonly used in clinical laboratories as described in the authorized procedures submitted as part of the EUA request.

Your product requires the following control materials, or other authorized control materials (as may be requested under Condition L. below), that are to be run as outlined in the authorized procedures submitted as part of the EUA request. All controls listed below must generate expected results in order for a test to be considered valid, as outlined in the authorized procedures submitted as part of the EUA request:

- Extraction Control – targeting human RNase P (RP) mRNA - controls for specimen quality and demonstrates that nucleic acid was generated by the extraction process.
- Positive Template Control - monitors the integrity of the PCR reagents and process.
- No Template (Negative) Control - Nuclease-free, molecular-grade water used to monitor non-specific amplification, cross-contamination during experimental setup, and nucleic acid contamination of reagents.

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 authorized labeling.

The labeling entitled “Simplicity COVID-19 Home Collection Kit Instructions”, “Simplicity COVID-19 Home Collection Kit” box label and the EUA Summary (available at https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas), the following standard operating procedures (SOPs) and instrument manuals: “Assurance Scientific Laboratories Sample Accessioning Protocol for the Simplicity COVID-19 Home Collection Kit”, “Assurance SARS-CoV-2 Panel/Assurance SARS-CoV-2 Panel DTC SOP”, “CFX96 and CFX384 Real-Time PCR Detection Systems Instruction Manual”, and the “CFX Maestro Software User Guide Version 1.1”, 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: Assurance Scientific Laboratories - Assurance SARS-CoV-2 Panel DTC
- Fact Sheet for Individuals: Assurance Scientific Laboratories - Assurance SARS-

CoV-2 Panel DTC

The Simplicity COVID-19 Home Collection Kit, with the "Simplicity COVID-19 Home Collection Kit Instructions" is authorized to be distributed and used as set forth in this EUA.

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.

IV. Conditions of Authorization

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

Assurance Scientific Laboratories (You) and Authorized Distributor(s) [8]

[8] "Authorized Distributor(s)" are identified by you, Assurance Scientific Laboratories, in your EUA submission as

A. Your product must comply with the following labeling requirements pursuant to FDA regulations: 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 available all instructions related to the self-collection of nasal swab specimens using the Simplicity COVID-19 Home Collection Kit and the Fact Sheet for Individuals both in the shipped kit and on your website.

C. You and authorized distributor(s) must make available on your website(s), if applicable, the authorized Fact Sheet for Healthcare Providers.

D. Through a process of inventory control, you and authorized distributor(s) must maintain records of the numbers and locations to which the Simplicity COVID-19 Home Collection Kit is distributed.

E. You and authorized distributor(s) must maintain customer complaint files on record. You will report to FDA any significant complaints about usability or deviations from the established performance characteristics of the product of which you become aware.

F. 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.

Assurance Scientific Laboratories (You)

G. You must provide authorized distributor(s), relevant public health authorities, and authorized laboratories with a copy of this EUA and communicate to authorized distributor(s), relevant public health authorities, and authorized laboratories any subsequent authorized revisions that might be made to this EUA and the authorized accompanying materials.

H. You must notify FDA of any authorized distributor(s) of the Simplicity COVID-19 Home Collection Kit including the name, address, and phone number of any authorized distributor(s).

I. You must ensure that authorized laboratories using your product have a process in place for reporting test results to relevant public health authorities, as appropriate. You must also ensure that authorized laboratories using your product have a process in place for providing test results via the agreed upon process as authorized by the Everlywell COVID-19 Test Home Collection Kit DTC and the Simplicity COVID-19 Home Collection Kit.

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an entity allowed to distribute the Simplicity COVID-19 Home Collection Kit.

J. You must maintain records of the authorized laboratories to which your distribute your product and test usage.

K. You must collect information on the performance of your product. You must report to 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 and false negative results and significant deviations from the established performance characteristics of your product of which you become aware.

L. 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, Any request for changes to this EUA should be submitted to the DMD/OHT7- OIR/OPEQ/CDRH and require appropriate authorization from FDA prior to implementation.

M. You must evaluate the analytical limit of detection and assess traceability[9] of your product with any FDA-recommended reference material(s). After submission to and concurrence with the data by FDA, you will update your labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7- OIR/OPEQ/CDRH.

N. You must submit to FDA a summary report within 30 calendar days of authorization summarizing the results of any testing performed using anterior nasal swab specimens collected with Simplicity COVID-19 Home Collection Kit for use with your product during that timeframe, including how many specimens were received, how many specimens had to be rejected during accession and the main reasons for rejection, and the positivity rate for specimens collected with the authorized collection kit.

O. 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.

P. If requested by FDA, you must update your labeling within 7 calendar days to include 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.

Q. You must have a process in place in accordance with 21 CFR Part 803 to track adverse

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

events, including any occurrence of false results with your product, including with the Everlywell COVID-19 Test Home Collection Kit DTC or the Simplicity COVID-19 Home Collection Kit and report any such events to FDA pursuant to 21 CFR Part 803. Serious adverse events, especially unexpected biosafety concerns, must immediately be reported to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov).

R. You must have a process in place for reporting all test results to individuals who use the Simplicity COVID-19 Home Collection Kit. This process must include a requirement that all positive and invalid/indeterminate results must be reported to individuals who self-collected specimens using the Simplicity COVID-19 Home Collection Kit by a HCP, defined in footnote 7.

S. You must have a healthcare provider available to provide information and counseling to individuals using the Simplicity COVID-19 Home Collection Kit. You will ensure these healthcare providers have the Fact Sheet for Healthcare Providers, for reference.

Authorized Laboratories

T. Authorized laboratories using your product will 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.

U. Authorized laboratories using your product must perform the test as outlined in the authorized labeling. Deviations from the authorized labeling, 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.

V. Authorized laboratories when testing anterior nasal swab specimens collected using the Simplicity COVID-19 Home Collection Kit or the Everlywell COVID-19 Test Home Collection Kit DTC authorized for use with your product must follow any specimen accessioning protocol provided with the collection kit when accepting specimens for testing.

W. Authorized laboratories must notify the relevant public health authorities of their intent to run your product.

X. Authorized laboratories using your product must have a process in place for reporting test results to relevant public health authorities, as appropriate. Authorized laboratories using your product must also have a process in place for reporting test results via the agreed upon process as authorized by the Everlywell COVID-19 Test Home Collection Kit DTC and the Simplicity COVID-19 Home Collection Kit.

Y. Authorized laboratories using your product 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 (clientservices@assurancescientific.com) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of the test of which they become aware.

Z. 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 the test in accordance with the authorized labeling.

Assurance Scientific Laboratories (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, and 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 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,

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RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosure