August 19, 2020

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

Device:	Assurance SARS-CoV-2 Panel
Company:	Assurance Scientific Laboratories
Indication:	Qualitative detection of nucleic acid from SARS-CoV-2 in nasal, nasopharyngeal or oropharyngeal swabs from individuals suspected of COVID-19 infection by their healthcare provider. This test is also intended for use with nasal swab specimens that are self-collected at home or in a healthcare setting by individuals using an authorized home-collection kit specified in this authorized test's authorized labeling, when determined to be appropriate by a healthcare provider. Emergency use of this test is limited to authorized laboratories.
Authorized Laboratories:	Testing is limited to laboratories designated by Assurance Scientific Laboratories that are also certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meet the requirements to perform high complexity tests.

Dear Dr. Massey:

On May 15, 2020, based on your[1] request, the Food and Drug Administration (FDA) issued a letter authorizing the emergency use of your product[2] for the qualitative detection of nucleic acid from SARS-CoV-2 in nasal, nasopharyngeal or oropharyngeal swabs from individuals suspected of COVID-19 infection by their healthcare provider, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3). The May 15, 2020, letter authorizing emergency use of this test, also authorized its use with nasal swab specimens that are self-collected at home or in a healthcare setting by individuals using an authorized home-collection kit specified in this authorized test's authorized labeling, when determined to be appropriate by a healthcare provider. Testing was limited to Assurance Scientific

[1] For ease of reference, this letter will use the term "you" and related terms to refer to Assurance Scientific Laboratories.
[2] For ease of reference, this letter will use the term "your product" to refer to the Assurance SARS-CoV-2 Panel used for the indications identified above.

Laboratories that is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests.

On July 30, 2020, you requested to revise your Emergency Use Authorization (EUA). Based on that request, and having concluded that revising the May 15, 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 May 15, 2020, 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, this test 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.[4]

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 Section 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

[3] The revisions to the May 15, 2020, letter include: (1) updating the authorizated laboratories to include laboratories designated by Assurance Scientific Laboratories that are also certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meet the requirements to perform high complexity tests, (2) add use of the Assurance COVID-19 Home Collection Kit to self-collect nasal swab specimens at home by individuals when determined to be appropriate by a healthcare provider, for use with your product, (3) added conditions of authorization specific to the addition of authorized laboratories designated by Assurance Scientific Laboratories, (4) update the healthcare provider and patient fact sheets to reflect more recent authorization, (5) update the authorized labeling documents to include patient instructions and specimen accessioning standard operating procedures specific to the Assurance COVID-19 Home Collection Kit, and (6) remove use of the N2 target primer/probe set from the Assurance SARS-CoV-2 Panel.

[4] 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).

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.[5]

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 a qualitative test for the detection of nucleic acid from SARS-CoV-2 in nasal, nasopharyngeal or oropharyngeal swabs from individuals suspected of COVID-19 infection.

Nasal specimens may also be self-collected at home or in a healthcare setting by individuals using an authorized self-collection kit, as specified in the authorized labeling, when determined to be appropriate by a healthcare provider. The "Assurance COVID-19 Home Collection Kit Instructions" for patients and "Assurance Scientific Laboratories Sample Accessioning Protocol for the Assurance COVID-19 Home Collection Kit" for laboratories are required to be distributed as specified in the conditions below (Section IV). Testing is limited to laboratories designated by Assurance Scientific Laboratories that are also certified under CLIA and meet the requirements to perform high-complexity tests.

The SARS-CoV-2 nucleic acid is generally detectable in respiratory specimens during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2 nucleic acid; 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. 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.

To use your product, SARS-CoV-2 nucleic acid is first extracted, isolated and purified from nasal, nasopharyngeal or oropharyngeal swabs. 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 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 (refer to Condition O. 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:

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

- 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 above described product is authorized to be accompanied with the labeling submitted as part of the EUA request, and as described in the EUA summary (available at https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations), and the following product-specific information pertaining to the emergency use, which is required to be made available to healthcare providers and patients:

- Fact Sheet for Healthcare Providers: Assurance Scientific Laboratories - Assurance SARS-CoV-2 Panel
- Fact Sheet for Patients: Assurance Scientific Laboratories - Assurance SARS-CoV-2 Panel

The above described product, when accompanied by the EUA Summary, Fact Sheet for Healthcare Providers, Fact Sheet for Patients, and the Assurance SARS-CoV-2 Panel SOP (collectively referenced as "authorized labeling") is authorized to be distributed and used by authorized laboratories, 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 authorized product, when used as described within and 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 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)

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 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 will make your product available with the authorized labeling to authorized laboratories. The Assurance COVID-19 Home Collection Kit Instructions and Assurance Scientific Laboratories Sample Accessioning Protocol for the Assurance COVID-19 Home Collection Kit will also be made available to authorized laboratories using the Assurnace COVID-19 Home Collection Kit.

C. You may request changes to the authorized labeling, Assurance COVID-19 Home Collection Kit Instructions, and Assurance Scientific Laboratories Sample Accessioning Protocol for the Assurance COVID-19 Home Collection Kit. Such requests will be made by you in consultation with, and require concurrence of, 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).

D. You will make available on your website(s) the authorized Fact Sheet for Healthcare Providers, Fact Sheet for Patients, and the "Assurance COVID-19 Home Collection Kit Instructions" patient insrtuctions.

E. You will 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. You will ensure that the authorized laboratories using your product have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.

G. You will maintain records of the of the laboratories you designate as authorized laboratories and you will also maintain records of test usage by all such authorized laboratories.

H. You 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.

I. You may request changes to the Scope of Authorization (Section II in this letter) of your product. Such requests will be made in consultation with DMD/OHT7-OIR/OPEQ/CDRH, and require concurrence of, Office of Counterterrorism and Emerging Threats (OCET)/Office of the Chief Scientist (OCS)/Office of the Commissioner (OC) and DMD/OHT7-OIR/OPEQ/CDRH.

J. You may request the addition of other home collection kits for use with your product, that will be named in the authorized labeling. Such requests will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

K. You may request the addition of other instruments and associated software for use with your product. Such requests will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

L. You may request the addition of other extraction methods for use with your product. Such requests will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

M. You may request the addition of other specimen types for use with your product. Such requests will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

N. You may request the addition and/or substitution of primers or probes for use with your product. Such requests will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

O. You may request the addition and/or substitution of control materials for use with your product. Such requests will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

P. You may request the addition and/or substitution of other ancillary reagents and

materials for use with your product. Such requests will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

Q. You may request the addition and/or substitution of the components of the Assurance COVID-19 Home Collection Kit, or any other home specimen collection kit authorized for use with your product. Such requests will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

R. You will evaluate the analytical limit of detection and assess traceability[6] of your product with any FDA-recommended reference material(s). After submission to FDA and DMD/OHT7-OIR/OPEQ/CDRH's review of and concurrence with the data, you will update labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

S. You will submit to FDA a summary report within 30 calendar days of authorization summarizing the results of any testing performed using specimens collected with any new home-collection kit authorized for use with your product, 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 home-collection kit.

T. You will track adverse events, including any occurrence of false results and report to FDA pursuant to 21 CFR Part 803.

U. You will additionally track adverse events associated with the Assurance COVID-19 Home collection kit, or any other home specimen collection kit authorized for use with your product, including occurrences of false results and report to FDA pursuant to 21 CFR Part 803. Serious adverse events, especially unexpected biosafety concerns, should immediately be reported to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov).

V. You will make available all instructions related to the self-collection of specimens using the Assurance COVID-19 Home collection kit, or any other home specimen collection kit authorized for use with your product, both in the shipped kit and on your website.

W. You will notfy FDA of any changes to the COVID-19 questionnaire used by a healthcare provider to determine eligbility of an individual to receive the Assurance COVID-19 Home collection kit, or any other home specimen collection kit authorized for use with your product.

Authorized Laboratories

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

X. 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.

Y. Authorized laboratories using your product will 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 ancillary reagents and authorized materials required to perform the test are not permitted.

Z. Authorized laboratories testing authorized specimens self-collected using the Assurance COVID-19 Home Collection Kit, or any other authorized home specimen collection kit with your product must follow any Specimens Accessioning protocols provided with the authorized self-collection kit and/or outlined in Assurance Scientific Laboratories' "Assurance Scientific Laboratories Sample Accessioning Protocol for the Assurance COVID-19 Home Collection Kit," when accepting specimens for testing.

AA. Authorized laboratories that receive your product must notify the relevant public health authorities of their intent to run the test prior to initiating testing.

BB. Authorized laboratories using your product will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.

CC. Authorized laboratories will 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.

DD. All laboratory personnel using the test 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) and Authorized Laboratories

EE. You and authorized laboratories using your product will 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

FF. All descriptive printed matter, including 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 the applicable requirements set forth in the Act and FDA regulations.

GG. No descriptive printed matter, including 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.

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

- This test has not been FDA cleared or approved;
- This test has been authorized by FDA under an EUA for use by authorized laboratories;
- This test has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens; and,
- This test 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 Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or 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