U.S. FOOD & DRUG ADMINISTRATION

May 24, 2022

Cynthia Phillips, Ph.D.
VP of Regulatory, Quality and Clinical Affairs
BioFire Defense, LLC
79 West 4500 South, Suite 14
Salt Lake City, UT 84107

Device:	BioFire COVID-19 Test
EUA Number:	EUA200044
Company:	BioFire Defense, LLC
Indications:	This test is authorized for the following indications for use: For certain authorized laboratories (see below) – the qualitative detection of nucleic acid from SARS-CoV-2 in non-pooled upper respiratory swab specimens (nasopharyngeal, oropharyngeal, mid-turbinate or anterior nasal) or lower respiratory specimens (induced or expectorated sputum, endotracheal aspirate, bronchoalveolar lavage or mini-bronchoalveolar lavage) from individuals suspected of COVID-19 by their healthcare provider. For certain authorized laboratories (see below) Qualitative detection of nucleic acid from SARS-CoV-2 in non-pooled saliva specimens collected without preservatives in a sterile container in a healthcare setting under the supervision of a healthcare provider from individuals suspected of COVID-19 by their healthcare provider. For certain authorized laboratories (see below) – the qualitative detection of nucleic acid from SARS-CoV-2 in pooled samples containing up to eight saliva specimens or up to eight upper respiratory specimens (i.e., nasopharyngeal, oropharyngeal, mid-turbinate or anterior nasal swabs) collected individually from individuals suspected of COVID-19 by their healthcare provider.
Authorized Laboratories:	Testing of non-pooled specimens is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, that meet the requirements to perform high or moderate complexity tests, and similarly qualified U.S. Department of Defense (DoD) and non-U.S. laboratories. Testing of pooled specimens is limited to DoD laboratories that meet the requirements to perform high complexity tests.

Dear Dr. Phillips:

On March 23, 2020, based on your[1] request, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for emergency use of the BioFire COVID-19 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, FDA reissued the EUA on December 4, 2020, March 12, 2021, June 17, 2021 and August 24, 2021.[3, 4, 5, 6] FDA also granted updates to the authorized labeling on April 30, 2020[7] and March 7, 2022.[8]

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[1] For ease of reference, this letter will use the term "you" and related terms to refer to BioFire Defense, LLC.

[2] The March 23, 2020, letter authorized the BioFire COVID-19 Test for the qualitative detection of nucleic acid from SARS-CoV-2 in nasopharyngeal swabs in transport media from individuals suspected of COVID-19 by their healthcare provider. Testing was limited to United States (U.S.) laboratories certified under CLIA, 42 U.S.C. § 263a, to perform moderate complexity tests, and in U.S. laboratories certified under CLIA to perform high complexity tests, or in similarly qualified non-U.S. laboratories.

[3] On December 4, 2020, the revisions to the March 23, 2020, letter and authorized labeling included: (1) adding the qualitative detection of nucleic acid from SARS-CoV-2 in pooled samples containing up to eight nasopharyngeal swabs collected individually in transport media from individuals suspected of COVID-19 by their healthcare provider in certain laboratories, and (2) making associated updates to the healthcare provider and patient fact sheets, and instructions for use.

[4] On March 12, 2021 the revisions to the December 4, 2020, letter and authorized labeling included: (1) the addition of oropharyngeal, mid-turbinate and anterior nasal swab specimens and induced or expectorated sputum, endotracheal aspirates, bronchoalveolar lavage and mini-bronchoalveolar lavage specimens as authorized specimen types, (2) the addition of normal saline or phosphate-buffered saline as additional transport media types, (3) modification of the Instructions for Use to change the order of the addition of buffer and specimen to the sample injection vial and to remove the "equivocal" call for test reporting and add limitations related to vaccinated individuals and performance with variants and, (4) addition of the BioFire SHIELD Control Kit as redeveloped external positive control material, (5) update of the intended use to include the additional specimen types, (6) update of the healthcare provider and patient fact sheets to include the additional specimen types and update of the of healthcare provider fact sheet to include information related to performance with circulating variants, and (7) addition of new Condition of Authorization D.

[5] On June 17, 2021, the revisions to the March 12, 2021, letter and authorized labeling included: (1) update the intended use and authorized labeling to include the original version of the BioFire COVID-19 Test (referred to a version v1.0) for testing non-pooled upper respiratory swab specimens (nasopharyngeal, oropharyngeal, mid-turbinate or anterior nasal) and pooled samples containing up to eight nasopharyngeal swabs (NPS) collected individually in transport media along with version v1.1 authorized as part of the March 12, 2021 reissue to the EUA, (2) addition of the BioFire COVID-19 Test instructions for use associated with v1.0, which includes the "BioFire COVID-19 Test Instructions for Use (v1.0)", "BioFire COVID-19 Test v1.0 Quick Guide", and the "BioFire External Control Kit v1.0 Quick Guide", as part of the authorized labeling, (3) update of the healthcare provider and patient fact sheets to reflect more recent authorizations and (4) addition of a new Condition of Authorization D. to account for distribution of the two versions of the BioFire COVID-19 Test (v1.0 and v1.1).

[6] On August 24, 2021, the revisions to the June 17, 2021, letter and authorized labeling included: (1) modification of the intended use to add individually tested saliva specimens collected without preservatives in a sterile container as an authorized specimen type (v1.1), and to expand specimen pooling to include all upper respiratory specimens (v1.0 and v1.1), (2) update the IFU to reflect the addition of saliva specimens and pooling of upper respiratory specimens, (3) revisions to the letter and Conditions of Authorization (Section IV) for the addition of new Conditions related to circulating variants (new Conditions R and S in August 24, 2021 letter), and (4) revisions to the Healthcare provider and Patient Fact Sheets to include information related to saliva testing and revisions to the Healthcare Provider fact sheet to include information on pooling of upper respiratory specimens.

[7] On April 30, 2020, your request was granted (1) to add a summary of additional clinical testing and to revise the clinical testing summary for clarity, (2) add revised concentration values to the Limit of Detection section, and (3) minor edits to formatting.

[8] On March 7, 2022, your request was granted to extend the shelf-life expiration date for version v1.1 to 15 months, when stored at the recommended storage temperature (18-30°C), based on the results of your ongoing stability studies.

On December 9, 2021, you requested to further revise your Emergency Use Authorization (EUA). Based on this request and having concluded that revising the August 24, 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 August 24, 2021, letter in its entirety with revisions incorporated.[9] 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[10] is now authorized for the indications set forth 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.[11]

FDA considered the totality of scientific information available in authorizing the emergency use of your product for the indications set forth above. A summary of the performance information FDA relied upon is included in the "BioFire COVID-19 Test Instructions for Use v1.1" (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:

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;

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[9] The revisions to the August 24, 2021, letter and authorized labeling include: (1) modification of the intended use to remove reference to versions v1.0 and v1.1, only v1.1 is being used going forward, (2) expand specimen pooling to include up to eight saliva specimens, (3) remove the v1.0 labeling, (4) unmask additional SARS-CoV-2 targets of the BioFire COVID-19 Test and associated updates to the IFU, Quick Reference Guides (performance sections and results interpretation) and software, (5) update the analytical performance with updated in silico analysis and additional cross-reactivity and interfering substances, (6) extend the shelf life from 15 to 18 months based on the results of ongoing stability studies, (7) update manufacturing lot release criteria during, and (8) revisions to the Healthcare provider and Patient Fact Sheets to include information on pooling and pooling of saliva specimens.

[10] For ease of reference, this letter will use the term "your product" to refer to the BioFire COVID-19 Test used for the indications identified above.

[11] 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).

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.[12]

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 indications above.

Authorized Product Details

Your product is a nested multiplexed RT-PCR test performed on the FilmArray 2.0 and FilmArray Torch Instrument Systems intended for the qualitative detection of nucleic acid from SARS-CoV-2 in non-pooled upper respiratory swab specimens (i.e., nasopharyngeal, oropharyngeal, mid-turbinate or anterior nasal) or lower respiratory specimens (induced or expectorated sputum, endotracheal aspirate, bronchoalveolar lavage or mini-bronchoalveolar lavage) collected from individuals suspected of COVID-19 by their healthcare provider. This product is also for use with saliva specimens collected without preservatives in a sterile container in a healthcare setting under the supervision of a healthcare provider. Testing of non-pooled specimens is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, that meet the requirements to perform high or moderate complexity tests, and similarly qualified U.S. Department of Defense (DoD) and non-U.S. laboratories.

Your product is also for the qualitative detection of nucleic acid from SARS-CoV-2 in pooled samples containing up to eight saliva specimens or up to eight upper respiratory specimens (i.e., nasopharyngeal, oropharyngeal, mid-turbinate or anterior nasal swabs)collected individually from individuals suspected of COVID-19 by their healthcare provider. Testing of pooled specimens is limited to DoD laboratories that meet the requirements to perform high complexity tests. Specimens should only be pooled in areas with low SARS-CoV-2 prevalence, and when testing demand exceeds laboratory capacity or reagent availability.

Results are for the identification of SARS-CoV-2 RNA. The SARS-CoV-2 RNA is generally detectable in upper respiratory, lower respiratory and saliva 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. Pooled samples with positive results must be tested individually prior to reporting results. The agent detected may not be the definite cause of disease.

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. Negative results from pooled samples should

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

be reported as presumptive. Specimens with low viral genetic material may not be detected in pooled samples due to decreased sensitivity. If clinical signs and symptoms are inconsistent with a negative result, the patient should be considered for individual testing.

Your product, when used with the FilmArray 2.0 and the Film Array Torch Instrument Systems, or other authorized instrument systems (as may be requested under Condition K. below), automates all aspects of nucleic acid testing including sample preparation, nucleic acid extraction and polymerase chain reaction (PCR) amplification using nested multiplex PCR, and detection of the SARS-CoV-2 targets sequences in a single-use cartridge. The BioFire COVID-19 Test includes the materials or other authorized materials (as may be requested under Condition K. below) required to perform testing with your product as described in the authorized labeling (described below).

Your product also includes, in the cartridge, controls, or other authorized controls, (as may be requested under Condition K. below), that are processed in the same way as the patient specimens as described in the authorized labeling (described below).

You recommend use of external controls, such as the BioFire SHIELD Control Kit for the Biofire COVID-19 Test which is not included with the kit but are available from you with the "BIOFIRE SHIELD Control Kit v1.1 Quick Guide for the BioFire COVID-19 Test" and electronically available "BIOFIRE SHIELD Control Kit for the BioFire COVID-19 Test Instructions for Use v1.1", used along negative controls, or other authorized controls (as may be requested under Condition K. below), which are to be run as outlined in the "BioFire COVID-19 Test Instructions for Use v1.1.".

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 "BioFire COVID-19 Test Instructions for Use v1.1."

The labeling entitled "BioFire COVID-19 Test Instructions for Use v1.1" (available at https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas), "BioFire COVID-19 Test v1.1 Quick Guide - For use with FilmArray 2.0 and Film Array Torch Systems (Upper Respiratory)" (for use with upper respiratory and saliva specimens), "BioFire COVID-19 Test v1.1 Quick Guide - For use with FilmArray 2.0 and Film Array Torch Systems (Lower Respiratory)," 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: BioFire Defense, LLC - BioFire COVID-19 Test
- Fact Sheet for Patients: BioFire Defense, LLC - BioFire COVID-19 Test

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 indications 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:

BioFire Defense, LLC (You) and Authorized Distributor(s)[13]

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

[13] "Authorized Distributor(s)" are identified by you, BioFire Defense, LLC, in your EUA submission as an entity allowed to distribute your product.

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 Fact Sheet for Healthcare Providers and the Fact Sheet for Patients.

D. You and authorized distributor(s) will include a physical copy of the "BioFire COVID-19 Test v1.1 Quick Guide - For use with FilmArray 2.0 and Film Array Torch Systems (Upper Respiratory)," (for use with upper respiratory and saliva specimens) and the "BioFire COVID-19 Test v1.1 Quick Guide - For use with FilmArray 2.0 and Film Array Torch Systems (Lower Respiratory)," with each shipped v1.1 version of your product to authorized laboratories, and will make the "BioFire COVID-19 Test Instructions for Use v1.1" 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/or 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 the test and number of tests they distribute.

G. You and authorized distributor(s) must collect information on the performance of your product. You will report to FDA 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.

BioFire Defense, LLC (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 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 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 and Radiological Health (OIR)/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 Part 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 traceability[14] 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.

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.

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

[14] Traceability refers to tracing analytical sensitivity/reactivity back to an FDA-recommended reference material. FDA may request, for example, that you perform this study in the event that we receive reports of adverse events concerning your product.

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.

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 authorized labeling. 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 report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and you (BioFire Defense Product Support website https://www.biofiredefense.com/product-support/filmarray-support/adverse-reporting-biofire-covid19-test/) 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.

Y. For pooled specimen testing, authorized laboratories must adhere to a protocol for ongoing monitoring of the pooling strategy or limit testing to individuals who are subjected to a detailed infection prevention and control plan.

Z. Authorized laboratories using specimen pooling strategies when testing patient specimens with your product must include with test result reports for specific patients whose specimen(s) were the subject of pooling, a notice that pooling was used during testing and that "*Patient specimens with low viral loads may not be detected in sample pools due to the decreased sensitivity of pooled testing*."

AA. Authorized laboratories implementing pooling strategies for testing patient specimens must use the "Specimen Pooling Implementation and Monitoring" available in the

authorized labeling to evaluate the appropriateness of continuing to use such strategies based on the recommendations in the protocol.

BB. Authorized laboratories must keep records of specimen pooling strategies implemented including type of strategy, date implemented, and quantities tested, and test result data generated as part of the Specimen Pooling Implementation and Monitoring protocol. For the first 12 months from the date of their creation, such records will be made available to FDA within 48 business hours for inspection upon request and will be made available within a reasonable time after 12 months from the date of their creation.

BioFire Defense, LLC (You), Authorized Distributor(s) and Authorized Laboratories

CC. 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

DD. 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.

EE. 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.

FF. 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,

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Jacqueline A. O'Shaughnessy, Ph.D.
Acting Chief Scientist
Food and Drug Administration

Enclosure