U.S. FOOD & DRUG ADMINISTRATION

April 11, 2022

Morteza Minaee
Head of Quality Assurance and Regulatory Affairs
Detect, Inc.
530 Old Whitfield Street
Guilford, CT 06437

Device:	Detect Covid-19 Test
EUA Number:	EUA210534
Company:	Detect, Inc.
Indication:	Non-prescription home use for the qualitative detection of nucleic acid from the novel coronavirus SARS-CoV-2 that causes COVID-19 with: Self-collected anterior nasal (nares) swab samples from individuals aged 14 years or older suspected of COVID-19. Adult-collected anterior nasal swab samples from individuals aged 2 years or older suspected of COVID-19 Self-collected anterior nasal swab samples from individuals aged 14 years or older and adult collected anterior nasal swab samples from individuals aged 2 years or older, without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over three days with at least 24 hours (and no more than 48 hours) between tests.

REVOKED

Dear Morteza Minaee:

On October 29, 2021, based on your[1] request the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for the Detect 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

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

stated in the letter.[2] Based on your request, FDA granted updates to the authorized labeling on January 12, 2022.[3]

On December 14, 2021, you requested to amend this EUA. Based on that request, and having concluded that revising the October 28, 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 October 28, 2021 letter in its entirety with the revisions incorporated.[4] Accordingly, your product[5] is hereby authorized pursuant to section 564 of the Act when used pursuant to the Scope of Authorization (Section II) and Conditions of Authorization (Section IV) of this reissued letter.

On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Act, the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes COVID-19. Pursuant to Section 564 of the Act, and on the basis of such determination, the Secretary of HHS then declared that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of the virus that causes COVID-19, subject to the terms of any authorization issued under Section 564 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 "Detect Covid-19 Test Covid-19 Molecular Home Test Instructions for Use For Healthcare Providers" identified below.

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[2] The October 28, 2021, letter authorized the Detect Covid-19 Test for the qualitative detection of nucleic acid from the novel coronavirus SARS-CoV-2 that causes COVID-19. Self-collected anterior nasal (nasal) swab samples from individuals aged 14 years or older suspected of COVID-19. Adult-collected anterior nasal swab samples from individuals aged 2 years or older suspected of COVID-19. Self-collected anterior nasal swab samples from individuals aged 14 years or older, or adult collected anterior nasal swab samples from individuals aged 2 years or older, without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over three days with at least 24 hours (and no more than 48 hours) between tests.

[3] On January 12, 2022, your request was granted to; (1) update the Detect Application (App) with the FDA agreed upon changes to fulfill Condition of Authorization Y. of the Letter of Authorization issued on October 28, 2021, that included addition of a user-facing Frequently Asked Questions section, and (2) update the Detect Covid-19 Test Covid-19 Molecular Home Test Instructions for Use For Healthcare Providers to include results of the near-cutoff study completed to fulfill Condition of Authorization U. of the Letter of Authorization issued on October 28, 2021. The revisions to the October 28, 2021, letter and authorized labeling include: (1) the option to use "Detect Covid-19 Test Covid-19 Instructions for Use" available to the end user electronically, (2) inclusion of a public health reporting feature for the "Detect App" to fulfilled Condition of Authorization T, in the October 28, 2021 letter, (3) extension of the kit expiration date to 8 months through real-time stability studies, (4) extension of the expiration date of the control component to 17 months based on data provided, (5) minor updates to the Fact Sheet for Healthcare Providers and the Fact Sheet for Individuals for consistency with more recent authorizations, (5) updates to the letter for consistency with language used in more recent authorizations, (6) addition of Condition of Authorization N. and (7) removal of Conditions of Authorization T., U., V., and Y. from the October 28, 2021 letter that were fulfilled through the submission of data and information to FDA..

[5] For ease of reference, this EUA will use the term "your product" to refer to the Detect Covid-19 Test 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).

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

I. Criteria for Issuance of Authorization

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

1. The SARS-CoV-2 can cause a serious or life-threatening disease or condition including severe respiratory illness, to humans infected by this virus;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that your product may be effective in diagnosing COVID-19, and 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 a molecular in vitro diagnostic test for the qualitative detection of nucleic acid from the novel coronavirus SARS-CoV-2 that causes COVID-19. This test is authorized for non-prescription home use with self-collected anterior nasal (nasal) swab samples from individuals aged 14 years or older suspected of COVID-19. This test is also authorized for non-prescription home use with adult-collected anterior nasal swab samples from individuals aged 2 years or older suspected of COVID-19. This test is also authorized for non-prescription home use with self-collected anterior nasal (nasal) swab samples from individuals aged 14 years or older, or adult collected anterior nasal swab samples from individuals aged 2 years or older, without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over three days with at least 24 hours (and no more than 48 hours) between tests.

The SARS-CoV-2 viral RNA is generally detectable in anterior nasal swab specimens during the acute phase of infection. Positive results indicate the presence of viral RNA, but clinical correlation with past 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. Individuals who test positive with the Detect Covid-19 Test should self-isolate and seek follow-up care with their physician or healthcare provider as additional testing may be necessary

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

Negative results should be treated as presumptive and confirmation with a molecular assay performed in a laboratory, if necessary for patient management, may be performed. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for treatment or management decisions for the individual, including infection control decisions. Negative results should be considered in the context of an individual's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19.

Individuals who test negative and continue to experience COVID-19 like symptoms of fever, cough and/or shortness of breath may still have SARS-CoV-2 infection and should seek follow up care with their physician or healthcare provider.

Test results will be reported to relevant public health authorities in accordance with local, state and federal requirements, using appropriate LOINC and SNOMED codes, as determined by the Laboratory In Vitro Diagnostics (LIVD) Test Code Mapping for SARS-CoV-2 Tests provided by the Centers for Disease Control and Prevention (CDC). Automatic test result reporting will be performed by the Detect App and the Detect secure cloud server.

The Detect Covid-19 Test includes the materials, or other authorized materials (as may be requested under Condition L. and N.), required to collect the anterior nasal (nares) swab sample and perform the test procedure, as described in the "Detect Covid-19 Test Covid-19 Molecular Home Test Instructions for Use For Healthcare Providers" and the "Detect Covid-19 Test Covid-19 Instructions for Use." Your product also requires use of the reusable Detect Hub device, provided separately from you along with the "Detect Hub User Manual."

Your product is performed using anterior nasal swab samples from individuals aged 2 years or older. The individual using your product has the option to follow the "Detect Covid-19 Test Covid-19 Instructions for Use" or follow digital, electronic-based step-by-step Detect Covid-19 Test Covid-19 instructions by downloading the "Detect App" mobile application (App) onto a compatible mobile smart phone device.[8]

Your product includes an internal control test line (Line 2) that must generate the expected result for a test to be considered valid, as outlined in the "Detect Covid-19 Test Covid-19 Molecular Home Test Instructions for Use For Healthcare Providers," the "Detect Covid-19 Test Covid-19 Instructions for Use" and in the step-by-step instructions provided in the Detect App.

The labeling entitled "Detect Covid-19 Test Covid-19 Molecular Home Test Instructions for Use For Healthcare Providers", the "Detect Covid-19 Test Covid-19 Instructions for Use," the "Detect Hub User Manual" and the "Detect Covid-19 Test" box labels[9] (available at

[8] Compatible smart phone includes Apple iPhone running Operation System (iOS) 13 or later versions of the iOS, and Android Phones Models released after 2013 and using the Android API level 26 (Android 8 or higher) with 720DPI or better resolution (720x1280px), including for example Samsung, Google, Motorola, Huawei, LG, Nokia, Alcatel and ZTE. Additional smart phone models as may be requested, and for which you receive appropriate authorization, in accordance with Condition M.

[9] "Detect Covid-19 Test" box labels include boxes for 1 test kit and "Detect Covid-19 Test" box labels for additional test kits numbers/options as may be requested, and for which you receive appropriate authorization, in accordance with Condition N. Detect Covid-19 Test numbers/options are described in the "Detect Covid-19 Test Covid-19 Molecular Home Test Instructions for Use For Healthcare Providers."

https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas), the "Detect App" software application 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 Professionals: Detect, Inc. - Detect Covid-19 Test
- Fact Sheet for Individuals: Detect, Inc. - Detect Covid-19 Test

The above described product, when accompanied by the authorized labeling as set forth in the Conditions of Authorization (Section IV) is authorized to be distributed and used under this EUA, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

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

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

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

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

III. Waiver of Certain Requirements

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

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

IV. Conditions of Authorization

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

Detect, Inc. (You) and Authorized Distributor(s)[10]

A. Your product must comply with the following labeling requirements: the intended use statement in 21 CFR 809.10(a)(2), (b)(2); adequate directions for use in 21 U.S.C. 352(f) and 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 the instructions for downloading the "Detect App" software application as part of your shipped kit using the "Detect Covid-19 Test" box labels (see Footnote 9) and make the "Fact Sheet for Individuals" and the "Detect Covid-19 Test Covid-19 Instructions for Use" for your product available electronically on your website(s).

C. You and authorized distributor(s) must make available the Detect Hub device with the "Detect Hub User Manual" instructions for use at the same time as your product and make the "Detect Hub User Manual" available electronically on your website.

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

E. You and authorized distributor(s) must inform relevant public health authorities of this EUA, including the terms and conditions herein, and any updates made to your product and/or the authorized labeling.

F. Through the process of inventory control, you and authorized distributor(s) must maintain records of the locations (e.g., pharmacies, doctor's offices, etc.) to which your product is distributed, and the number of tests distributed.

G. You and authorized distributor(s) must collect information on the performance of your product and have a process in place to track adverse events, including any occurrence of false positive or false negative results and significant deviations from the established performance characteristics of the product of which you become aware and report any such events to FDA in accordance with 21 CFR Part 803. Serious adverse events, especially unexpected biosafety concerns, should immediately be reported to Division of Microbiology (DMD)/Office of Health Technology 7 (OHT7)-Office of In Vitro

[10] "Authorized Distributor(s)" are identified by you, Detect, Inc., in your EUA submission as an entity allowed to distribute the Detect Covid-19 Test.

Diagnostics and Radiological Health (OIR)/Office of Product Evaluation and Quality (OPEQ)/Center for Devices and Radiological Health (CDRH) (via email: CDRH-EUAReporting@fda.hhs.gov).

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.

I. You and authorized distributor(s) 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.

Detect, Inc. (You)

J. You must notify FDA of any authorized distributor(s) of your product, including the name, address, and phone number of any authorized distributor(s).

K. You must provide authorized distributor(s) with a copy of this EUA and communicate to authorized distributor(s) any subsequent revisions that might be made to this EUA and its authorized accompanying materials, including the authorized labeling.

L. You must make the authorized "Detect Covid-19 Test Covid-19 Molecular Home Test Instructions for Use For Healthcare Providers," the "Detect Covid-19 Test Covid-19 Instructions for Use," and the Fact Sheet for Healthcare Professionals electronically available on your website. Additionally, you must provide the opportunity to request a copy of the "Detect Covid-19 Test Covid-19 Molecular Home Test Instructions for Use For Healthcare Providers," the "Detect Covid-19 Test Covid-19 Instructions for Use," and Fact Sheet for Healthcare Professionals in paper form, and after such request, promptly provide the requested labeling at no additional cost.

M. You may request changes to this EUA for your product, including to the Scope of Authorization (Section II in this letter) or to the authorized labeling, including requests to make available additional authorized labeling specific to an authorized distributor. Such additional labeling may use another name for the product but otherwise must be consistent with the authorized labeling and shall not exceed the terms of authorization of this letter. Any request for changes to this EUA should be submitted to DMD/OHT7-OIR/OPEQ/CDRH and require appropriate authorization from FDA prior to implementation.

N. You may request new box labels to allow additional test kits numbers/options for your product. Such additional labeling requests to this EUA should be submitted to and require concurrence of DMD/OHT7-OIR/OPEQ/CDRH prior to implementation.

O. 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).

P. You must have lot release procedures and the lot release procedures, including the study design and statistical power, must ensure that the product released for distribution meet the clinical and analytical performance claimed in the authorized labeling.

Q. If requested by FDA, you must submit your 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 them within 48 hours of the request.

R. You must evaluate the analytical limit of detection and assess traceability[11] 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.

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

T. You must complete the agreed upon real-time stability study for your product and notify DMD/OHT7-OIR/OPEQ/CDRH of the testing results. After submission of the study data, and review and concurrence with the data by FDA, you must update your product labeling to reflect the additional testing if requested by FDA. Such labeling updates must be made in consultation with and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

U. 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-MDRReporting@fda.hhs.gov).

V. 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.

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

Conditions Related to Printed Materials, Advertising and Promotion

W. 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.

X. 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.

Y. 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;
- This product has been authorized only for the detection of nucleic acid from SARS- CoV-2, not for any other viruses or pathogen;
- 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