U.S. FOOD & DRUG ADMINISTRATION

April 6, 2022

Patrick Ashley
Senior Deputy Director
DC Department of Health
899 North Capitol Street NE
Washington, DC 20002

Device:	Test Yourself DC At-Home COVID-19 Collection Kit
EUA Number:	EUA210634
Company:	DC Department of Health ("DC Health")
Indication:	This product is authorized for the following indications for use: For direct to consumer (DTC) collection of anterior nasal swab specimens at home for testing with Labcorp's COVID-19 RT-PCR Test. For use by any individuals age 18 years and older (self-collected), 14 years and older (self-collected under adult supervision), or 2 years and older (collected with adult assistance), including individuals without symptoms or other reasons to suspect COVID-19. Qualitative detection of nucleic acid from SARS-CoV-2 in pooled samples using a matrix pooling strategy (i.e., group pooling strategy), containing up to five individual upper respiratory swab specimens (nasopharyngeal, mid-turbinate, anterior nasal or oropharyngeal swabs collected using individual vials containing transport media) per pool and 25 specimens per matrix. Emergency use of Labcorp's COVID-19 RT-PCR Test is limited to the authorized laboratory.
Authorized Laboratory:	Testing of specimens collected using the Test Yourself DC At-Home COVID-19 Collection Kit using Labcorp's COVID-19 RT-PCR Test is limited to the Center for Esoteric Testing in Burlington, NC which is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meets the requirements to perform high complexity tests.

Dear Mr. Ashley:

This letter is in response to your[1] request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for emergency use of your product,[2] pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3).

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.[3]

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:

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.[4]

[1] For ease of reference, this letter will use the term "you" and related terms to refer to DC Department of Health ("DC Health").
[2] For ease of reference, this letter will use the term "your product" to refer to the Test Yourself DC At-Home COVID-19 Collection Kit used for the indication identified above.
[3] 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).
[4] No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

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 authorized as a direct-to-consumer product for collection of anterior nasal swab specimens at home from individuals age 18 years and older (self-collected), 14 years and older (self-collected under adult supervision), or 2 years and older (collected with adult assistance), including individuals without symptoms or other reasons to suspect COVID-19, for testing with Labcorp's COVID-19 RT-PCR Test. Anterior nasal swab specimens collected with the Test Yourself DC At-Home COVID-19 Collection Kit are also authorized to be tested with Labcorp's COVID-19 RT-PCR Test, for the qualitative detection of nucleic acid from the SARS-CoV-2 in pooled samples, using a matrix pooling strategy (i.e., group pooling strategy), containing up to five individual upper respiratory swab specimens (nasopharyngeal, mid-turbinate, anterior nasal or oropharyngeal swabs collected using individual vials containing transport media) per pool and 25 specimens per matrix.

Testing of specimens collected using the Test Yourself DC At-Home COVID-19 Collection Kit using Labcorp's COVID-19 RT-PCR Test is limited to the Center for Esoteric Testing in Burlington, NC which is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meets the requirements to perform high complexity tests.

All test results are delivered to the user via an online DC Health patient information system as well as via email (and text message, if opted in). The direct-to-consumer home collection system is intended to enable users to access information about their COVID-19 status that could aid with determining if self-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. Negative results do not preclude SARS-CoV-2 infection.

Additionally, negative results from pooled testing should not be treated as definitive and may need follow up testing if inconsistent with an individual's signs and symptoms. Specimens included in pools where the positive sample cannot be identified using the matrix must be tested individually prior to reporting a result. Specimens with low viral loads may not be detected in sample pools due to the decreased sensitivity of pooled testing.

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

The Test Yourself DC At-Home COVID-19 Collection Kit provides specimen collection materials and materials to safely drop-off specimens for accessioning and shipment to the authorized laboratory for testing using Labcorp's COVID-19 RT-PCR Test. Individuals should follow all specimen collection and specimen drop-off instructions provided in the kit.

To perform the COVID-19 RT-PCR Test, SARS-CoV-2 nucleic acid is first extracted, isolated and purified from anterior nasal swab specimens collected with the Test Yourself DC At-Home COVID-19 Collection Kit. The purified nucleic acid is then reverse transcribed into cDNA followed by PCR amplification and detection using an authorized real-time (RT) PCR instrument.

Your product uses all commercially sourced materials or other authorized materials and authorized ancillary reagents commonly used in clinical laboratories as described in the authorized labeling for Labcorp's COVID-19 RT-PCR Test. Your product requires control materials that are described in the authorized labeling for Labcorp's COVID-19 RT-PCR Test.

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 for Labcorp's COVID-19 RT-PCR Test.

Your product, described above, is authorized to be accompanied with the labeling listed below, 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), and the following fact sheets pertaining to the emergency use, which are required to be made available to healthcare providers and individuals:

- Fact Sheet for Healthcare Providers: DC Health - Test Yourself DC At-Home COVID-19 Collection Kit
- Fact Sheet for Individuals: DC Health - Test Yourself DC At-Home COVID-19 Collection Kit

The above described product, when accompanied by the EUA Summary, the two fact sheets, the "Test Yourself DC At-Home COVID-19 Collection Kit: Collection Instructions", the "Test Yourself DC At-Home COVID-19 Collection Kit" box label, and the following standard operating procedures (SOPs): "Automated Aliquot and 4x4 Sample Pooling" which includes the "Protocol for Monitoring of Specimen Pooling Testing Strategies," "Test Yourself DC At-Home COVID-19 Collection Kit (TYS) - Accessioning SOP," "Nucleic Acid Isolation for COVID-PCR Kingfisher Flex System," "Nucleic Acid Isolation for COVID-PCR on the Hamilton MicroLab STAR," and the "SARS-CoV-2 Detection by Nucleic Acid Amplification (Labcorp EUA – 384 Well Multiplex)" is authorized to be used by the Center for Esoteric Testing, Burlington, NC, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

The Test Yourself DC At-Home COVID-19 Collection Kit, with the "Test Yourself DC At-Home COVID-19 Collection Kit: Collection Instructions" and the "Test Yourself DC At-Home COVID-19 Collection Kit" box label, is authorized to be distributed and used as set forth in this

EUA.

"Authorized Labeling" refers to the EUA Summary for the Test Yourself DC At-Home COVID-19 Collection Kit, the two fact sheets described herein, the "Test Yourself DC At-Home COVID-19 Collection Kit: Collection Instructions", the "Test Yourself DC At-Home COVID-19 Collection Kit" box label, and the "Test Yourself DC At-Home COVID-19 Collection Kit (TYS) – Accessioning SOP".

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:

DC Health (You) and Authorized Distributor(s)[5]

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 collection of anterior nasal swab specimens using the Test Yourself DC At-Home COVID-19 Collection Kit (i.e., "Test Yourself DC At-Home COVID-19 Collection Kit: Collection Instructions") and the Fact Sheet for Individuals both in the provided kit using the "Test Yourself DC At-Home COVID-19 Collection Kit" box labeling and on your website.

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

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

E. 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.

DC Health (You)

F. You must notify FDA of any authorized distributor(s) of the Test Yourself DC At-Home COVID-19 Collection Kit, including the name, address, and phone number of any authorized distributor(s).

G. You must provide authorized distributor(s) and the authorized laboratory with a copy of this EUA and communicate any subsequent amendments that might be made to this EUA and its authorized accompanying materials.

H. You must inform the authorized laboratory and relevant public health authorities of this EUA, including the terms and conditions herein, and any updates made to your product and authorized labeling.

[5] "Authorized Distributor(s)" are identified by you, DC Health, in your EUA submission as an entity allowed to distribute the Test Yourself DC At-Home COVID-19 Collection Kit.

I. You must ensure that the authorized laboratory using your product has a process in place for reporting test results to you, individuals, and relevant public health authorities, as appropriate.

J. You, when accepting specimens collected using the Test Yourself DC At-Home COVID-19 Collection Kit, must follow your "Test Yourself DC At-Home COVID-19 Collection Kit (TYS) - Accessioning SOP" prior to sending specimens to the authorized laboratory.

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: CDRHEUA-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, 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 DMD/OHT7-OIR/OPEQ/CDRH and require appropriate authorization from FDA prior to implementation.

M. You must submit to FDA a summary report within 30 calendar days of authorization summarizing the results of any testing performed using specimens collected with Test Yourself DC At-Home COVID-19 Collection Kit 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.

N. 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. 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).

O. You must have a process in place for reporting all test results to individuals who use the Test Yourself DC At-Home COVID-19 Collection Kit. This process must include access to customer support to provide general information and recommend consulting with their healthcare provider, as appropriate. This process must ensure the Fact Sheet for Individuals and the Fact Sheet for Healthcare Providers are made available to individuals with the test result, for example via weblink.

Authorized Laboratory

P. The authorized laboratory must perform the test as outlined in the authorized labeling for Labcorp's COVID-19 RT-PCR Test. Deviations from the authorized labeling for Labcorp's COVID-19 RT-PCR Test, 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.

Q. The authorized laboratory testing specimens collected using the Test Yourself DC At-Home COVID-19 Collection Kit must have in place a suitable specimen receipt and accessioning standard operating procedure when accepting specimens for testing.

R. The authorized laboratory must notify the relevant public health authorities of their intent to run the test prior to initiating testing.

S. The authorized laboratory must have a process in place for reporting test results to relevant public health authorities, as appropriate.

T. The authorized laboratory 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 (testingresults@dc.gov) any suspected occurrence of false positive or false negative results linked to the use of your product and significant deviations from the established performance characteristics of your product of which they become aware.

U. The authorized laboratory testing specimens collected with the Test Yourself DC At-Home COVID-19 Collection Kit must have a process in place for reporting all test results to DC Health.

V. The authorized laboratory, when using specimen pooling strategies when testing individual's specimens with your product must include with test result reports for individuals whose specimen(s) were pooled, 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*."

W. The authorized laboratory, when implementing pooling strategies for testing individual's specimens must use the "Protocol for Monitoring of Specimen Pooling Testing Strategies" provided in the authorized labeling for Labcorp's COVID-19 RT-PCR Test to evaluate the appropriateness of continuing to use such strategies based on the recommendations in the protocol.

X. The authorized laboratory 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 Protocol for Monitoring of Specimen Pooling Testing Strategies. 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.

Y. 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 for Labcorp's COVID-19 RT-PCR Test.

DC Health (You), Authorized Distributor(s) and Authorized Laboratory

Z. You, authorized distributor(s) and the authorized laboratory using your product must ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records must be made available to FDA for inspection upon request.

Conditions Related to Printed Materials, Advertising and Promotion

AA. 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.

BB. 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.

CC. 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 the authorized laboratory;
- 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 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 during the COVID-19 outbreak 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